~~Small Biotech Exception and Biosimilar Delay~~ Negotiation Program Drug Selection for Initial Price Applicability Year 2028
under Sections 11001 and 11002 of the Inflation Reduction Act
Information Collection Request (ICR) Forms ~~for Initial Price Applicability Year 2027~~

(CMS-10844, OMB 0938-1443)

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act ~~(~~("the Act~~).~~").

This ~~Small Biotech Exception and Biosimilar Delay Information Collection Request~~ Negotiation Program Drug Selection for Initial Price Applicability Year ~~2027~~ 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) includes ~~two~~three parts: Part 1 (Small Biotech Exception ~~Information Collection Request~~ICR Form~~) and~~), Part 2 (Biosimilar Delay ~~Information Collection Request~~ICR Form~~).~~), and Part 3 (Identification and Selection of Renegotiation-Eligible Drugs ICR Form).

Terms used in this ~~information collection request (ICR)~~ICR have the meaning set forth in the Medicare Drug Price Negotiation Program: ~~Final~~Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year ~~2027~~2028 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026, 2027, and ~~2027~~2028 (expected to be issued in ~~Fall 2024~~Spring 2025 concurrently with this ICR; referenced hereinafter as the "~~final~~draft guidance~~")~~[1]~~.~~").

PART 1

Small Biotech Exception ~~Information Collection Request~~ICR Form

In accordance with section 1192(d)(2) of the Act, the term "negotiation-eligible drug" excludes, with respect to initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs (the "Small Biotech Exception~~,""~~" or "SBE").

~~In order to~~ CMS needs to collect information to accurately identify, at the request of a manufacturer ("Submitting Manufacturer"), whether a given qualifying single source drug qualifies for the SBE ~~for~~. Only the entity that currently holds the New Drug Application(s) (NDA)(s) or Biologics License Applications(s) (BLA)(s) for the qualifying single source drug may be the Submitting Manufacturer for this ICR.

For initial price applicability year ~~2027 in accordance~~2028, section 1192(d) of the Act requires CMS to evaluate whether a qualifying single source drug qualifies for the SBE based on Medicare expenditures under Part D or Part B. CMS intends to make separate determinations

[1] ~~Available at: https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf~~.

with respect to the Part D criteria pursuant to section 1192(d)(2)(A)(i) of the Act (the "Part D Track") and the Part B criteria pursuant to section 1192(d)(2)(A)(ii) of the Act (the "Part B Track"). For initial price applicability year 2028, the term "negotiation-eligible drug" will exclude any qualifying single source drug that meets either the Part B or Part D criteria to qualify for the SBE.

For the purposes of the SBE, CMS needs to collect information to accurately identify the Part D 2021 Manufacturer and/or the Part B 2021 Manufacturer, as applicable. The Part D 2021 Manufacturer is the entity that had ~~a~~the Medicare Coverage Gap Discount Program (CGDP) Agreement under section 1860D-14A ~~for the for the drug~~ in effect for the qualifying single source drug on December 31, 2021 ~~(the "~~. The Part B 2021 Manufacturer~~"), including all other entities~~ is the entity that~~, as of~~ held the NDA(s) / BLA(s) for the qualifying single source drug on December 31, 2021. In addition, the aggregation rule at section 1192(d)(2)(B)(i) of the Act requires that CMS treat as a single manufacturer all corporations or partnerships, sole proprietorships, and other entities that, on December 31, 2021, were treated as a single employer ~~with that entity~~(i.e., part of the same controlled group) under subsection (a) or (b) of section 52 of the Internal Revenue Code ~~(IRC)~~ of 1986 (IRC) with the Part D 2021 Manufacturer or Part B 2021 Manufacturer. The controlled group of the Part D 2021 Manufacturer comprises all entities that, as of December 31, 2021, were treated as a single employer with the Part D 2021 Manufacturer and had a ~~Medicare~~ CGDP Agreement in effect on December 31, 2021. ~~Accordingly,~~CMS also collects information regarding the unique identifier assigned by CMS (P Number) and labeler code(s) for ~~the purpose of the SBE, "~~these entities. The controlled group~~"~~ of the Part B 2021 Manufacturer ~~means~~comprises all ~~corporations or partnerships, sole proprietorships, and other entities~~entities that, as of December 31, 2021, were treated as a single employer with the Part B 2021 Manufacturer ~~under section 52(a) or (b) of~~. CMS also collects information regarding the NDA(s) and/or BLA(s) for qualifying single source drugs held by the ~~IRC~~Part B 2021 Manufacturer and the ~~Department of the Treasury regulations thereunder.~~

Part B 2021 Manufacturer's controlled group on December 31, 2021. Additionally, the limitation at section 1192(d)(2)(B)(ii) of the Act states that a qualifying single source drug is not eligible for an SBE if the ~~manufacturer~~Submitting Manufacturer of such drug is acquired after 2021 by another entity that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(C)(ii~~)~~[2]~~. Because the~~). [3] The earliest effective date for this limitation is January 1, 2025

[2] ~~*See* section 50.1 of the Medicare Part D Manufacturer Discount Program Final Guidance, dated November 17, 2023, available at https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf, and, *see also*, the November 17, 2023 HPMS memorandum titled, "Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers", available at https://www.cms.gov/files/document/manufacturer-discount-program-specified-and-specified-small-manufacturer-methodology.pdf, for more information.~~

[3] *See* section 50.1 of the Medicare Part D Manufacturer Discount Program Final Guidance, dated December 20, 2024, available https://www.cms.gov/files/document/revised-manufacturer-discount-programfinal-guidance122024.pdf, and, *see also*, the November 17, 2023 HPMS memorandum titled, "Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers", available at https://www.cms.gov/files/document/manufacturer-discount-program-specified-and-specified-small-manufacturer-methodology.pdf, for more information.

for acquisitions prior to January 1, 2025, ~~this requirement applies to requests for the SBE starting in initial price applicability year 2027~~or January 1, 2026, for acquisitions occurring during 2025.

~~Note: A Submitting Manufacturer must submit a request for an SBE for initial price applicability year 2027 regardless of whether the manufacturer submitted a request for initial price applicability year 2026.~~Note: This ICR only collects information relevant to a manufacturer's request for the SBE for initial price applicability year ~~2027.~~2028. A Submitting Manufacturer seeking to be considered for the SBE for initial price applicability year 2028 must submit a request for an SBE for initial price applicability year 2028 regardless of whether the manufacturer submitted a request for a prior initial price applicability year. A determination by CMS that a given qualifying single source drug qualifies for an SBE for initial price applicability year 2027 does not mean that this drug will continue to qualify for an SBE for initial price applicability year 2028. ~~The Submitting Manufacturer must submit a request for the drug to be considered for the SBE for initial price applicability year 2028.~~

A determination by CMS that a given qualifying single source drug qualifies for the SBE for initial price applicability year 2028 does not determine if the drug will qualify for the temporary floor for a small biotech drug that is selected for initial price applicability years 2029 or 2030 as described in section 1194(d) of the Act. CMS will provide information about section 1194(d) of the Act in future rulemaking.

Instructions:

- A Submitting Manufacturer must complete and submit the information requested on this form in order for the drug to be considered for ~~the exception for initial price applicability year 2027~~an SBE for initial price applicability year 2028. For a qualifying single source drug to be considered under the Part D Track, a Submitting Manufacturer should complete Section A, Section B, and Section D; to be considered under the Part B Track, a Submitting Manufacturer should complete Section A, Section C, and Section D; to be considered under both the Part D Track and Part B Track, a Submitting Manufacturer should complete Section A, Section B, Section C, and Section D.
- A separate form must be submitted for each qualifying single source drug for which the Submitting Manufacturer seeks the SBE. The definition of a qualifying single source drug is described in section 30 of the draft guidance.
- As described in section 30.2.1 of the ~~final~~draft guidance, to the extent that more than one entity meets the statutory definition of a manufacturer of a qualifying single source drug, only the holder of the ~~New Drug Application(s) (NDA)(s) or Biologics License Applications(s) (BLA)(~~NDA(s) / BLA(s) for the qualifying single source drug may be the Submitting Manufacturer.
- If the Submitting Manufacturer holding the NDA~~/~~(s) / BLA(s) for the drug was acquired by another entity after December 31, 2021, the Submitting Manufacturer must provide information regarding that acquiring entity for CMS to assess whether the acquisition triggers the limitation at section 1192(d)(2)(B)(ii).

- ~~If the Submitting Manufacturer seeks the Small Biotech Exception for a qualifying single source drug it acquired after December 31, 2021, the Submitting Manufacturer must also submit information related to the separate entity that had the CGDP Agreement for the drug on December 31, 2021.~~
- ~~A separate form must be submitted for each qualifying single source drug for which the Submitting Manufacturer seeks the SBE.~~
- Submitting Manufacturers will submit a request for an SBE for initial price applicability year ~~2027~~2028 via the CMS Health Plan Management System (the "CMS HPMS~~).~~").
- Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the CMS Health Plan Management System (CMS HPMS~~)~~") for the Medicare Drug Price Negotiation Program" PDF.[4] Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.[5] Technical assistance will also be made available.
- ~~Requests~~A request for an SBE that ~~are~~is incomplete or not timely submitted via the CMS HPMS in accordance with these instructions and applicable guidance will not be accepted.
- All submissions require certification. ~~This form must be completed and submitted within~~The certification of the ~~CMS HPMS~~ICR should be executed by (1) the ~~date specified by CMS in program instruction.~~chief executive officer (CEO) of the Submitting Manufacturer; (2) the chief financial officer (CFO) of the Submitting Manufacturer; (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO of the Submitting Manufacturer; or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).
- To complete this form, the Submitting Manufacturer must provide the following:
  - Identifying information about the Submitting Manufacturer as of the date of submission, including the Submitting Manufacturer's name, Employer Identification Number(s) (EIN(s)), mailing address, and the unique identifier(s) assigned by CMS to the Submitting Manufacturer (P number(s)[6]~~), and all labeler codes;~~);
  - Disclosure of whether the Submitting Manufacturer holding the NDA~~/~~(s) / BLA(s) for the drug was acquired by another entity after 2021, and if so, identifying information about the acquiring entity as of the date of submission, including the acquiring entity's name, ~~Employer Identification Number(s) (~~EIN(s~~)),~~ and mailing address, as well as any P number(s)~~ and labeler codes~~ of the acquiring entity;
  - Identifying information about the qualifying single source drug for which the Submitting Manufacturer seeks the SBE:
    - Active moiety (for drug products) or active ingredient (for biological products);

[4] https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-cms-health-plan-management-system-cms-hpms-medicare.pdf.

[5] ~~https://www.cms.gov/about-cms/information-systems/hpms/user-id-process.~~

[6] A P number is a unique identifier assigned by CMS when the manufacturer enters into an agreement under section 1860D-14A or 1860D-14C of the Act. CMS uses P Numbers to identify manufacturer accounts in the CMS HPMS for various programs such as the Manufacturer Discount Program, the Medicare Drug Price Negotiation Program, the Medicare Prescription Drug Inflation Rebate Program, and the Medicare Part B Discarded Drug Program.

- All NDAs held by the Submitting Manufacturer for any drug products with the active moiety or all BLAs held by the Submitting Manufacturer for any biological products with the active ingredient; and

- Under the Part D track:
  - Identifying information as of December 31, 2021 for the entity that had a Medicare CGDP Agreement for the qualifying single source drug covered under Part D in effect on December 31, 2021, and for all members of that entity's controlled group that had a Medicare CGDP Agreement in effect on December 31, 2021~~.~~; and/or

- ~~All submissions that are incomplete or not timely submitted will not be accepted. For a submission to be timely for initial price applicability year 2027, the Small Biotech Manufacturer must submit a complete exception form to CMS via the CMS HPMS by the date specified by CMS.~~ Under the Part B track:
  - Identifying information as of December 31, 2021 for the entity that held the NDA(s) / BLA(s) for
    - ~~All submissions require certification.~~ The certification of the ~~ICR should be executed by (1) the chief executive officer (CEO)~~qualifying single source drug paid under Part B as of ~~the~~ December 31, 2021, and all NDA(s) and/or BLA(s) held by that entity and its controlled group as of December 31, 2021.

A. Submitting Manufacturer~~, (2) the chief financial officer (CFO) of~~ and Qualifying Single Source Drug Information

Section A contains three questions regarding the Submitting Manufacturer and qualifying single source drug, including information related to an acquiring manufacturer if the Submitting Manufacturer~~, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO~~ was acquired after December 31, 2021 and information related to the active moiety / active ingredient and list of NDA(s) / BLA(s) associated with the qualifying single source drug for which the Submitting Manufacturer~~, or (4) an individual with the directly delegated authority to perform~~ is requesting the SBE.

Question 1: Information on the ~~certification on behalf of one of the individuals mentioned in (1) through (3).~~Submitting Manufacturer

~~**Questions:**~~

Instructions for Question 1: Please provide the following information about the Submitting Manufacturer as of the date of submission of this form~~:~~. The Submitting Manufacturer must be the current holder of the NDA(s) or BLA(s) for the qualifying single source drug.

Field	Response
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Mailing Address	Text
Unique Identifier Assigned by CMS (P number)[7]	Pnnnn
~~Labeler Code(s)~~	~~Nnnnn~~

Question 2: Acquisition of the Submitting Manufacturer

Instructions for Question 2a: Was the Submitting Manufacturer ~~holding~~, the ~~New Drug Application (~~entity that currently holds the NDA(s) or ~~Biologics License Applications (~~BLA~~)~~(s) for the qualifying single source drug for which you seek the Small Biotech Exception, acquired after December 31, 2021?

Yes/No

Note: If the answer to question 2a is 'Yes,' answer Question 2b. If the answer to Question 2a is 'No,' skip to Question 3a.

Instructions for Question 2b: If you answered "Yes" to Question 2a above, please provide the following information about the ~~acquiring entity.~~entity that acquired the Submitting Manufacturer.

Field	Response
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Address	Text
Unique Identifier Assigned by CMS (P number), if any	Pnnnn
~~Labeler Code(s), if any~~	~~Nnnnn~~

[7] A P number is a unique identifier assigned by CMS when the manufacturer enters into an agreement under section 1860D-14A or 1860D-14C of the Act. CMS uses P Numbers to identify manufacturer accounts in the CMS HPMS for various programs such as the Medicare Drug Price Negotiation Program, the Medicare Prescription Drug Inflation Rebate Program, Manufacturer Discount Program, and the Medicare Part B Discarded Drug Program.

Question 3: Qualifying Single Source Drug Information

Instructions for Question 3a: Please list the active moiety (for drug products~~) or~~), active ingredient (for biological products) or distinct combination of active moieties / active ingredients for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception.

Active Moiety / Active Ingredient
Text

Instructions for Question 3b: Please list all ~~New Drug Applications (NDAs~~NDA(s) held by the Submitting Manufacturer for any drug products with the active moiety(ies) listed in Question 3a or all ~~Biologics License Applications (BLAs~~BLA(s) held by the Submitting Manufacturer for any biological products with the active ingredient(s) listed in Question 3a, as applicable, for which the Submitting Manufacturer is requesting a Small Biotech Exception. Additional rows may be added if needed.

Application Number (123456)	Application Type (NDA; BLA)	Approval Date	NDA/BLA holder
Nnnnnn	Select NDA or BLA	MM/DD/YYYY	Text

Add a separate row for each additional NDA / BLA.

B. Part D Track: Information for Qualifying Single Source Drugs Covered Under Part D

If requesting the SBE under the Part D Track for the qualifying single source drug, please complete Section B of this ICR in its entirety. Otherwise, please skip to the Part B Track in Section C.

Section B contains two questions for the SBE determination under the Part D track for a qualifying single source drug that is covered under Part D. Section B contains one question about the entity that had a Coverage Gap Discount Program Agreement in effect for the qualifying single source drug as of December 31, 2021 ("Part D 2021 Manufacturer"). The other question collects information about the members of that entity's controlled group (if any) as of December 31, 2021.

Question 4: Part D 2021 Manufacturer Coverage Gap Program Agreement Information

Instructions for Question 4a: On December 31, 2021, did the Submitting Manufacturer have a Coverage Gap Discount Program Agreement in effect for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception?[8]

[8] A manufacturer that participated in the CGDP in 2021 by means of an arrangement whereby its labeler codes were listed on another manufacturer's CGDP Agreement would be considered to have had an agreement in effect during 2021.

Yes/No

Note: If the answer to Question 4a is 'No,' answer Question 4b~~.~~ and skip Question 4c. If the answer to Question 4a is 'Yes,' skip ~~to~~ Question ~~5a~~4b and answer Question 4c.

Instructions for Question 4b: Please provide the following information as of December 31, 2021 about the entity that had a Coverage Gap Discount Program Agreement in effect on December 31, 2021, for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception.

Field	Response
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Address	Text
Unique Identifier Assigned by CMS (P number) if any	Pnnnn
Labeler Code(s) owned by this entity that are associated with this entity's unique identifier (P number)	
Labeler Code(s) owned by this entity that are associated with unique identifier(s) (P number(s)) owned by other entities, if any	

Instructions for Question 4c: Please provide the following information as of December 31, 2021 about the Submitting Manufacturer.

Field	Response
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Address	Text
Unique Identifier Assigned by CMS (P number) if any	Pnnnn
Labeler Code(s) owned by this entity that are associated with this entity's unique identifier (P number)	
~~Labeler Code(s)~~Labeler Code(s) owned by this entity that are associated with unique identifier(s) (P number(s)) owned by other entities, if any	~~Nnnnn~~

Question 5: Part D 2021 Manufacturer Controlled Group Information

Instructions for Question 5a: Did the entity that had a Coverage Gap Discount Program Agreement in effect on December 31, 2021~~,~~ for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception (i.e., either the Submitting Manufacturer or the entity identified in Question 4b, as applicable) have other members in its controlled group as of December 31, 2021~~,~~ that had a Medicare Coverage Gap Discount Program

Agreement in effect on December 31, 2021? For the purpose of this information collection request, "controlled group" means all corporations or partnerships, sole proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986.

Yes/No

Note: If the answer to Question 5a is 'Yes,' answer Question 5b. If the answer to Question 5a is 'No,' skip ~~to certification.~~ Question 5b and proceed to Section C (if applying for the Part B Track) or certification to complete the Part D Track.

Instructions for Question 5b: If yes, provide the following information as of December 31, 2021, for **each such** member of the controlled group of the entity that had the Coverage Gap Discount Program Agreement in effect on December 31, 2021, for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception.

Field	**Response**
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Address	Text
Unique Identifier Assigned by CMS (P number) if any	Pnnnn
Labeler Code(s) owned by this entity that are associated with this entity's unique identifier (P number)	
~~Labeler Code(s)~~Labeler Code(s) owned by this entity that are associated with unique identifier(s) (P number(s)) owned by other entities, if any	~~nnnnn~~

Add a separate entry with the ~~five~~six data elements for each member of the entity's controlled group.

C. Part B Track: Information for Qualifying Single Source Drugs Paid Under Part B

If requesting the SBE under the Part B Track for the qualifying single source drug, please complete Section C of this ICR in its entirety. Otherwise, please skip to Section D.

Section C contains two questions that pertain to information required to make a determination under the Part B Track for a qualifying single source drug that is payable under Part B. Section C contains questions about the entity that held the NDA(s) or BLA(s) for the qualifying single source drug as of December 31, 2021 ("Part B 2021 Manufacturer"). Section C also contains questions that collect information about the NDA(s) or BLA(s) held by that entity and the members of that entity's controlled group (if any).

Question 6: 2021 NDA/BLA Holder Information

Instructions for Question 6a: On December 31, 2021, did the Submitting Manufacturer hold the NDA(s) / BLA(s) for the qualifying single source drug for which you seek the Small Biotech Exception?

Yes/No

Note: If the answer to Question 6a is 'Yes,' skip to Question 6d. If the answer to Question 6a is 'No,' answer Question 6b and Question 6c, and skip Question 6d.

Instructions for Question 6b: Please provide the following information as of December 31, 2021 about the entity that held the NDA(s) or BLA(s) on December 31, 2021 for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception.

Field	**Response**
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Address	Text
Unique Identifier Assigned by CMS (P number) if any	Pnnnn

Instructions for Question 6c: Please list the NDA(s) and/or BLA(s) that were held as of December 31, 2021 by the entity that held the NDA(s) or BLA(s) on December 31, 2021 for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception (i.e., the entity identified in Question 6b). List all NDA(s) and/or BLA(s), including for drugs and biological products other than the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception.

Application Number (123456)	**Application Type (NDA; BLA)**	**Approval Date**	**NDA/BLA holder**
Nnnnnn	Select NDA or BLA	MM/DD/YYYY	Text

Add a separate row for each additional NDA / BLA.

Instructions for Question 6d: Please list all NDA(s) and/or BLA(s) held by the Submitting Manufacturer as of December 31, 2021, including for drugs and biological products other than the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception.

Application Number (123456)	**Application Type (NDA; BLA)**	**Approval Date**	**NDA/BLA holder**
Nnnnnn	Select NDA or BLA	MM/DD/YYYY	Text

Add a separate row for each additional NDA / BLA.

Question 7: Part B 2021 Manufacturer Controlled Group Information

Instructions for Question 7a: Did the entity that held the NDA(s) or BLA(s) on December 31, 2021 for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception (i.e., either the Submitting Manufacturer or the entity identified in Question 6b, as applicable) have other members in its controlled group as of December 31, 2021? For this information collection request, "controlled group" means all corporations or

partnerships, sole proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986.

Yes/No

Note: If the answer to Question 7a is 'Yes,' answer Question 7b. If the answer to Question 7a is 'No,' skip to certification.

Instructions for Question 7b: If yes, provide the following information as of December 31, 2021, for **each such** member of the controlled group of the entity.

Field	**Response**
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Address	Text
NDA(s) and/or BLA(s) the entity held as of December 31, 2021	nnnnnn

Add an additional row for each NDA and BLA the entity held as of December 31, 2021.

Add a separate entry with the four data elements for each member of the entity's controlled group.

D. Certification

In accordance with section 1192(d)(2) of the Act, the manufacturer of a small biotech drug ("Submitting Manufacturer") may submit a request for an SBE for a given initial price applicability year. As described in section 30.2.1 of the draft guidance, the Submitting Manufacturer eligible to submit the request is the holder of the NDA(s) or BLA(s) for the qualifying single source drug.

Read the following statement and check the box if accurate:

I confirm that I am an authorized representative of the Submitting Manufacturer of the qualifying single source drug named in this Small Biotech Exception Request and am submitting this Small Biotech Exception Request on behalf of the Submitting Manufacturer of the qualifying single source drug named in this Small Biotech Exception Request.

Check box for attestation: [ ]

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare reimbursement purposes, including to determine whether the qualifying single source drug of the Submitting Manufacturer qualifies for the Small Biotech Exception, as described in section 1192(d)(2) of the Social Security Act. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has

changed. or is otherwise inaccurate. I also understand that any misrepresentations may also give rise to liability, including under the False Claims Act. and/or in the form of civil monetary penalties pursuant to section 1196(a)(7) of the Act.

Check box for certification: [ ]

Contact Information

Field	Response
Name of the Person Responsible for the Submission	(information is prepopulated by CMS based on the CMS HPMS user information)
Signature	Text
Date	Date

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1443 (Expires XX/XX/XXXX)** ~~Yes/No~~

~~**Contact Information**~~

~~Field~~	~~Response~~
~~Name of the Person Responsible for the Submission~~	~~Text~~
~~Signature~~	~~Text~~
~~Date~~	~~Date~~

~~**PRA Disclosure Statement**~~

~~According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1443 (Expires 11/30/2025)**.~~ This is a required information collection to retain or obtain a benefit. Specifically, a manufacturer must submit the ICR in order for its qualifying single source drug to be considered for the SBE. The time required to complete this information collection is estimated to average ~~8.25~~9.75 hours per response for Submitting Manufacturers ~~that had a CGDP Agreement for such qualifying single source drug in effect and were not acquired after December 31, 2021, 10.25 per response for Submitting Manufacturers that had a CGDP Agreement for such qualifying single source drug in effect and were acquired after December 31, 2021, 16 hours for the Submitting Manufacturers that did not have a CGDP Agreement for such qualifying single source drug in effect and were not acquired after December 31, 2021, and 18 hours for the Submitting Manufacturer that did not have a CGDP Agreement for such qualifying single source drug in effect and were acquired after December 31, 2021, including the time~~ to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

PART 2

Biosimilar Delay ~~Information Collection~~ICR Form

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act ~~(~~(“the Act~~).~~”). In accordance with section 1192(f)(1)(B) of the Act, the manufacturer of a

biosimilar biological product ("Biosimilar Manufacturer" of a "Biosimilar") may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a "Reference Drug") on the selected drug list for a given initial price applicability year (the "Biosimilar Delay").

Section 1192(f) of the Act contemplates two potential requests under the Biosimilar Delay: (1) a request to delay the inclusion of a Reference Drug by one initial price applicability year ("Initial Delay Request"), as stated in section 1192(f)(1)(B)(i)(I) of the Act; and (2) a request to delay the inclusion of a Reference Drug for which an Initial Delay Request has been granted for a second initial price applicability year ("Additional Delay Request") as stated in section 1192(f)(1)(B)(i)(II) of the Act. CMS did not grant any Initial Delay Requests for initial price applicability year ~~2026~~2027; therefore, no Reference Drugs would be the subject of an Additional Delay Request in initial price applicability year ~~2027~~2028.

In accordance with section 30.1 of the ~~final~~draft guidance, in order for CMS to determine if the requirements in section 1192(f) of the Act for an Initial Delay Request are met, the Biosimilar Manufacturer must submit ~~identifying~~ information and make attestations as follows:

1. Identifying information for the Biosimilar Manufacturer, the Biosimilar, the Biosimilar's reference product, and the manufacturer of the Reference Drug (Reference Manufacturer~~;~~);
2. Attestation that the Biosimilar Manufacturer ~~must~~is not ~~be~~ the same as the Reference Manufacturer and ~~must~~is not ~~be~~ treated as being the same pursuant to section 1192(f)(1)(C) of the Act;
3. Attestations that the Biosimilar Manufacturer and the Reference Manufacturer ~~must~~have not ~~have~~ entered into an agreement that either:
    a) requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request; or
    b) directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time. For Initial Delay Requests submitted with respect to initial price applicability year ~~2027~~2028, CMS will consider any agreement between the Biosimilar Manufacturer and the Reference Manufacturer that directly or indirectly restricts the quantity of the Biosimilar that the Biosimilar Manufacturer may sell during any period of time on or after February 1, ~~2025~~2026, as violating this requirement;
4. Information on the status of licensure for the Biosimilar under section 351(k) of the Public Health Service Act ("PHS Act");
5. All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
6. The manufacturing schedule for the Biosimilar submitted to the Food and Drug Administration (FDA) during its review of the application for licensure under section 351(k) of the PHS Act, if submitted; and

7. All of the Biosimilar Manufacturer's disclosures pertaining to the marketing of the Biosimilar (e.g., in filings with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 or comparable documentation distributed to the shareholders of privately held companies) about capital investment, revenue expectations, and other actions typically taken by a manufacturer in the normal course of business in the year before marketing of a biosimilar biological product.

Note: This ICR only collects information relevant to a manufacturer's request for the Biosimilar Delay for initial price applicability year ~~2027~~2028.

A determination by CMS that a Reference Drug is removed from the list of negotiation-eligible drugs due to an Initial Delay Request for initial price applicability year ~~2027~~2028 does not mean that such Reference Drug will continue to qualify for the Biosimilar Delay for an Additional Delay Request for a second initial price applicability year (initial price applicability year ~~2028~~2029). The process for submitting an Initial Delay Request for initial price applicability year ~~2028~~2029 and for submitting an Additional Delay Request will be addressed in future guidance or rulemaking and a future ICR.

Instructions:

- Biosimilar Manufacturers will submit an Initial Delay Request for initial price applicability year ~~2027~~2028 via the CMS Health Plan Management System (the "CMS HPMS~~.~~[9]"). Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the CMS Health Plan Management System (CMS HPMS~~)~~") for the Medicare Drug Price Negotiation Program" PDF[10]. Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.[11] Technical assistance will also be made available.
- As described in section 30.3.1 of the ~~final~~draft guidance, the Biosimilar Manufacturer eligible to submit the request is the holder of the Biologics License Application (BLA) for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA for the Biosimilar that has been submitted for review by FDA. If neither the Biosimilar has been licensed nor the BLA has been submitted to the FDA, the Biosimilar Manufacturer eligible to submit the request is the organization planning to be the sponsor of the BLA submitted for review by the FDA.
- Initial Delay Requests that are incomplete or not timely submitted will not be accepted. For an Initial Delay Request to be timely for initial price applicability year ~~2027~~2028, the

~~[9] The new automated tool for the Biosimilar Delay is scheduled to be available by Fall 2024; in the event that its completion is delayed, CMS will use the same submission process deployed for initial price applicability year 2026, which relied on e-mail and a secured Box location for uploading of necessary files. Refer to the Supporting Statement – Part A for this ICR for additional information.~~

[10] https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-cms-health-plan-management-system-cms-hpms-medicare.pdf.

~~[11] https://www.cms.gov/about-cms/information-systems/hpms/user-id-process.~~

Biosimilar Manufacturer must submit a complete Initial Delay Request to CMS via the CMS HPMS by the date specified by CMS. CMS will deem an Initial Delay Request to be incomplete if it does not include the following documentation:

- All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
- The manufacturing schedule for the Biosimilar submitted to the Food and Drug Administration during its review of the application for licensure under section 351(k) of the Public Health Service Act, if submitted; and
- All of the Biosimilar Manufacturer's disclosures pertaining to the marketing of the Biosimilar (e.g., in filings with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 or comparable documentation distributed to the shareholders of privately held companies) about capital investment, revenue expectations, and other actions typically taken by a manufacturer in the normal course of business in the year before marketing of a biosimilar biological product.

- A separate form must be submitted for each Biosimilar with a separate BLA for which the Biosimilar Manufacturer requests an Initial Delay Request.
- All submissions require certification. The certification of the Initial Delay Request should be executed by (1) the chief executive officer (CEO) of the Biosimilar Manufacturer~~,~~; (2) the chief financial officer (CFO) of the Biosimilar Manufacturer~~,~~; (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO of the Biosimilar Manufacturer~~,~~; or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).
- The CMS HPMS response fields are limited to a maximum character count. Field sections provide a character count and a corresponding estimated word count if a free text field is included. Spaces between words are included in the character count.

Questions:

Section 1: Identifying information

Identifying information for Biosimilar Manufacturer

Question 1. Provide the following identifying information for the Biosimilar Manufacturer.

Field	Response
Entity Name	-Text
Employer Identification Number (EIN(s))	nn-nnnnnnn
Address	-Text

Field	Response
Unique Identifier Assigned by CMS (P number[12])	Pnnnn
~~Labeler Code(s)~~	~~Nnnnn~~

Identifying information on Biosimilar

Question 2. Provide the following identifying information for the Biosimilar.

Field	Response
Biosimilar Name	-Text
Active Ingredient	-Text

Question 3. List ~~all applications~~the application for licensure for the Biosimilar under section 351(k) of the Public Health Service Act regardless of status (i.e., including ~~applications that are~~if an application is approved, accepted for review, and submitted but not yet accepted for review). Select the current status and relevant date. If no application has been submitted, select that Question 3 is not applicable.

~~*Additional rows may be added if necessary within the CMS HPMS.*~~

Application Number	Submission Number	Application status	Relevant Date	Indication	Dosage Form and Strength	~~Licensure planned before February 1, 2027~~	~~Marketing planned before February 1, 2027~~
nnnnnn	nnn	Select the current status: ☐Approved ☐Accepted for Review ☐Submitted		Text	Text	~~Yes/No~~	~~Yes/No~~

[ ] Not applicable

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Identifying information on Reference Product and Reference Manufacturer

Question 4. Provide the following identifying information for the reference product for the Biosimilar and the Reference Manufacturer (i.e., holder of the Biologic License Application for the reference product).

[12] A P number is a unique identifier assigned by CMS when the manufacturer enters into an agreement under section 1860D-14A or 1860D-14C of the Act. CMS uses P Numbers to identify manufacturer accounts in the CMS HPMS for various programs such as the Manufacturer Discount Program, the Medicare Drug Price Negotiation Program, the Medicare Prescription Drug Inflation Rebate Program, and the Medicare Part B Discarded Drug Program.

Field	Response
-Reference Product	-Text
-Reference Manufacturer	Text

Question 5. Provide the following information for the BLA of the reference product, including the holder of the BLA.

Application Number-(123456)	Approval Date	BLA Holder
Nnnnnn	MM/DD/YYYY	Text

Section 2: Attestations to Requirements for Granting an Initial Delay Request

In accordance with section 1192(f)(2)(D)(iv) of the Act, CMS will not delay inclusion of a biological product on the list of selected drugs if the Biosimilar Manufacturer meets any of the statutory criteria for an excluded manufacturer. Questions 6 through 8 address whether the Biosimilar Manufacturer is an excluded manufacturer.

Question 6. Relationship between Biosimilar Manufacturer and Reference Manufacturer: In accordance with section 1192(f)(2)(D)(iv) of the Act, CMS will not approve an Initial Delay Request if the Biosimilar Manufacturer is the same as the Reference Manufacturer or is treated as being the same as the Reference Manufacturer based on the aggregation rule in section 1192(f)(1)(C) of the Act. This aggregation rule provides, "all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or in a partnership, shall be treated as one manufacturer" for purposes of the Biosimilar Delay. Further, section 1192(f)(1)(C)(ii) of the Act establishes that "the term 'partnership' means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on" by two or more parties for the purposes of the Biosimilar Delay.

Read the following statement and check the box if accurate:

I confirm consistent with sections 1192(f)(1)(C) and 1192(f)(2)(D)(iv) of the Act that the Biosimilar Manufacturer submitting this request is not the same and is not treated as being the same as the Reference Manufacturer named in this request.	☐

Question 7. Incentives: In accordance with section 1192(f)(2)(D)(iv)(II)(aa) of the Act, CMS will not approve any Initial Delay Request submitted by a Biosimilar Manufacturer that has entered into an agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(2)(D)(iv)(II)(aa) of the Act that the Biosimilar Manufacturer submitting this request has not entered into an agreement with the Reference Manufacturer named in this request that requires or incentivizes the Biosimilar Manufacturer to submit this or any other Initial Delay Request.	☐

Question 8. Quantity Restriction: In accordance with section 1192(f)(2)(D)(iv)(II)(bb) of the Act, CMS will not approve any Initial Delay Request submitted by a Biosimilar Manufacturer that has entered into an agreement with the Reference Manufacturer that restricts the quantity, either directly or indirectly, of the Biosimilar that may be sold in the United States over a specified period of time.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(2)(D)(iv)(II)(bb) of the Act that the Biosimilar Manufacturer submitting this request has not entered into an agreement with the Reference Manufacturer named in this request that restricts the quantity, either directly or indirectly, of the Biosimilar that may be sold in the United States over a specified period of time.	☐

In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year ~~2027~~2028 if CMS determines there is a high likelihood that the Biosimilar will be licensed and marketed before February 1, ~~2027~~2028 (additional information regarding this determination is included in section 30.3.1 of the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year ~~2027~~2028 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026, 2027, and ~~2027 (available at:).~~2028. Questions 9 and 10 are relevant for this determination.

Question 9. Licensure: In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year ~~2027~~2028 if CMS determines there is a high likelihood that the Biosimilar will be licensed before February 1, ~~2027~~2028. For the purposes of this Initial Delay Request, 'licensed' means approved by the Food and Drug Administration under section 351(k) of the Public Health Service Act.

Select the following option that best describes the current licensure status of the Biosimilar as of the submission of this Initial Delay Request (**only one of the following options may be selected**). *Biosimilar Manufacturers who select Option C or Option D have until 11:59 ~~p.m.~~ PM Pacific Time (PT) on January 15, ~~2025~~2026, to update CMS on the status of the Biosimilar's application for licensure.*

(A) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the Public Health Service Act and the Biosimilar has been licensed.	~~☐~~ ☐
(B) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the Public Health Service Act and the Food and Drug Administration has accepted such application for review.	~~☐~~ ☐
(C) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section	~~☐~~ ☐

(A) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the Public Health Service Act and the Biosimilar has been licensed.	~~☐~~ ☐
351(k) of the Public Health Service Act and has not received a determination from Food and Drug Administration that such application has been accepted for review.	
(D) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has not submitted an application for licensure of the Biosimilar under section 351(k) of the Public Health Service Act.	~~☐~~ ☐

If the Biosimilar Manufacturer selects Option A in Question 9, answer Question 10. If the Biosimilar Manufacturer selects Options B, C, or D in Question 9, skip to Section 3.

Question 10. Marketing: In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year ~~2027~~2028 if CMS determines there is a high likelihood that the Biosimilar will be marketed before February 1, ~~2027~~2028.

Select the following option that best describes the current marketing status of the Biosimilar as of the submission of this Initial Delay Request (**only one of the following options may be selected**):

(A) I confirm consistent with section 1192(f)(1)(A) of the Act, the Biosimilar is currently marketed.	☐
~~(B) I confirm consistent with section 1192(f)(1)(A) of the Act, the Biosimilar has not yet been marketed but the Biosimilar Manufacturer expects it to be marketed by February 1, 2027.~~	~~☐~~
(~~C~~B) I confirm consistent with section 1192(f)(1)(A) of the Act, the Biosimilar has not yet been marketed ~~and the Biosimilar Manufacturer does not expect it to be marketed by February 1, 2027.~~.	☐

Section 3: Supporting Documentation

Question 11. Manufacturing schedule: In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include, to the extent available, the manufacturing schedule for the Biosimilar submitted to the Food and Drug Administration during its review of the Biosimilar's application for licensure.

Upload the manufacturing schedule(s) for the Biosimilar submitted to the Food and Drug Administration for each application listed in Question 3. If no supporting documentation is available, check the box and provide an explanation of why supporting documentation was not available.

No supporting documentation is available □	Explanation: Text (2,400 character count limit, which is approximately 200 words)

Question 12. Disclosures: In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include, to the extent available, all of the Biosimilar Manufacturer's disclosures pertaining to the marketing of the Biosimilar (e.g., in filings with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 or comparable documentation distributed to the shareholders of privately held companies) about capital investment, revenue expectations, and other actions typically taken by a manufacturer in the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product.

Upload the disclosure(s) that pertain to the marketing for the Biosimilar. If no supporting documentation is available, check the box and provide an explanation of why supporting documentation was not available.

No supporting documentation is available □	Explanation: Text (2,400 character count limit, which is approximately 200 words)

Supporting documentation submitted includes documentation distributed to the shareholders of privately held companies that is comparable to filings with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 □	Explanation of how the documentation submitted is comparable: Text (2,400 character count limit, which is approximately 200 words)

Question 13. Agreements: In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include all agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Upload the agreement(s) related to the Biosimilar. If no supporting documentation is available, check the box and provide an explanation of why supporting documentation was not available.

No supporting documentation is available □	Explanation: Text (2,400 character count limit, which is approximately 200 words)

Section 4: Certification

In accordance with section 1192(f)(1)(B) of the Act, the Biosimilar Manufacturer may submit the request for a Biosimilar Delay for a given initial price applicability year. As described in section 30.3.1 of the draft guidance, the Biosimilar Manufacturer eligible to submit the request is the holder of the BLA for the Biosimilar, is the sponsor of the BLA submitted for review by the FDA or, if neither the Biosimilar has been licensed nor the BLA has been submitted to the FDA,

the Biosimilar Manufacturer eligible to submit the request is the organization planning to be the sponsor of the BLA submitted for review by the FDA.

Read the following statement and check the box if accurate:

I confirm that I am an authorized representative of the Biosimilar Manufacturer of the Biosimilar named in this Initial Delay Request and am submitting this Initial Delay Request on behalf of the Biosimilar Manufacturer of the Biosimilar named in this Initial Delay Request.

Check box for attestation: [ ]

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare reimbursement purposes, including to determine whether CMS should delay the selection of a biological product that would, absent this request, be included on the selected drug list for initial price applicability year ~~2027,~~2028 as described in section 1192(f) of the Social Security Act. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed~~.~~ or is otherwise inaccurate. I also understand that any misrepresentations may also give rise to liability, including under the False Claims Act~~.~~ and/or in the form of civil monetary penalties pursuant to section 1196(a)(7) of the Act.

Check box for certification: [ ]

Contact Information

Field	**Response**
Name of the Person Responsible for the Submission	(information is prepopulated by CMS based on the CMS HPMS user information)
Signature	Text
Date	Date

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1443 (Expires** ~~Yes/No~~

xx/xx/xxxx)~~ **Contact Information**~~

~~**Field**~~	~~**Response**~~
~~Name of the Person Responsible for the Submission~~	~~Text~~
~~**Signature**~~	~~**Text**~~
~~**Date**~~	~~**Date**~~

~~PRA Disclosure Statement~~

~~According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1443 (Expires 11/30/2025).~~ This is a required information collection to retain or obtain a benefit. Specifically, a Biosimilar Manufacturer must submit the Biosimilar Delay Information Collection Request in order for a Biosimilar to be considered for the Biosimilar Delay. The time required to complete this information collection is estimated to average 26 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

PART 3

Identification and Selection of Renegotiation-Eligible Drugs ICR Form

Section 1194(f) of the Social Security Act ("the Act") establishes the requirements governing the identification of renegotiation-eligible drugs, the selection of drugs for renegotiation, and the renegotiation process. CMS will identify renegotiation-eligible drugs in accordance with section 1194(f)(2) of the Act, as described in section 130.1 of the draft guidance. Next, CMS will select certain renegotiation-eligible drugs for renegotiation in accordance with section 1194(f)(3) of the Act, as described in section 130.2 of the draft guidance. Finally, CMS will renegotiate the maximum fair price (MFP) for such drugs selected for renegotiation, in accordance with section 1194(f)(4) of the Act, as described in section 130.4 of the draft guidance.

This information collection request (ICR) offers Primary Manufacturers[13] the voluntary option to submit information to CMS to inform CMS' determinations of which selected drugs qualify as a renegotiation-eligible drug and may be selected for renegotiation in accordance with sections 1194(f)(2)(A), 1194(f)(2)(D), and 1194(f)(3)(C) of the Act.

Note: This ICR focuses on information that may be submitted for selected drugs from initial price applicability years 2026 and 2027 for the identification and selection of renegotiation-eligible drugs for initial price applicability year 2028.

General Instructions

- All questions included in this ICR Form are optional. However, if the Primary Manufacturer responds to a series of questions that includes a free response explanation field for a reported numerical value in the same question series, the Primary Manufacturer must provide an explanation if the Primary Manufacturer reports a numerical value in the same series.
- These "General Instructions" and the "Additional Instructions" below apply to this entire ICR Form, in addition to any question-specific instructions. If a term included in this ICR Form is also included and defined in the draft guidance, the term's definition in this form is the same as in the draft guidance. Definitions otherwise included in this form are intended for purposes related to this form and the Medicare Drug Price Negotiation Program only. Questions about the draft guidance, including questions about terms defined in this ICR Form should be sent to IRARebateandNegotiation@cms.hhs.gov.
- Do not report any data or costs that were previously reported to CMS under a previous data submission. Information reported in this ICR Form should only include data not previously reported to CMS, following the specific question instructions for each section.
- All response fields are limited to a character count. The field and response format sections provide a character count and an estimated word count. Character counts are inclusive of all characters, including spaces between words.
- This submission should be completed by an individual authorized by the Primary

[13] To the extent that more than one entity meets the statutory definition of manufacturer (specified in section 1193(a)(1) of the Act) for a selected drug for purposes of initial price applicability year 2028, CMS will designate the entity that holds the New Drug Application(s) (NDA(s)) / Biologics License Application(s) (BLA(s)) for the selected drug to be "the manufacturer" of the selected drug (hereinafter the "Primary Manufacturer").

Manufacturer.

- The certification of the submission must be executed by (1) the chief executive officer (CEO) of the Primary Manufacturer; (2) the chief financial officer (CFO) of the Primary Manufacturer; (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Submission Method

Submission of the email included as an Appendix to this ICR Form (which is also described in section 130.3.1 of the draft guidance) indicating the Primary Manufacturer's intent to submit this ICR Form for initial price applicability year 2028 should be sent to CMS by the date and time to be specified by CMS upon approval from the Office of Management and Budget for this information collection. CMS will provide access to a specific Box folder for a Primary Manufacturer prior to the Primary Manufacturer's submission of any information included in response to the questions in this ICR Form to CMS.

Additional Instructions

- The Primary Manufacturer should provide data **only with regard to a selected drug identified** under section 1192 of the Act for initial price applicability year 2026 or 2027 with an agreed-upon MFP. If a Primary Manufacturer has more than one selected drug for which it chooses to submit information to inform renegotiation eligibility and selection, the Primary Manufacturer must submit separate submissions for each selected drug. If a selected drug will have a change in monopoly status to a long-monopoly drug, such drug will automatically be selected for renegotiation per section 1194(f)(3)(B) of the Act, and any voluntary submissions under this form by the Primary Manufacturer with regard to such drug will not inform CMS' determinations of such drug's eligibility or selection for renegotiation.
- The Primary Manufacturer should submit, if applicable to the questions in a section, the applicable data for *all* dosage forms and strengths of the selected drug, including for dosage forms and strengths that were sold, labeled, or packaged by a Secondary Manufacturer.[14]
  - Section 50.1 of the draft guidance includes information regarding a Primary Manufacturer's obligation to provide information about new 11-digit National Drug Codes (NDC-11s) marketed by the Primary Manufacturer or any Secondary Manufacturer(s).
  - When providing data to CMS about the selected drug, a Primary Manufacturer should include NDC-11s of the selected drug that may be payable under Part B (if any) but are not covered under Part D.
- For non-monetary numeric amounts, include up to three decimal places.
- Response formats are indicated within any charts (e.g., # to indicate a numerical response is required).

[14] For initial price applicability year 2028, CMS intends to refer to any other entity that meets the statutory definition of manufacturer for a drug product included in the selected drug and that either: (1) is listed as a manufacturer in an NDA or BLA for the selected drug; or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer but is not listed on the NDA or BLA as a "Secondary Manufacturer." A Secondary Manufacturer will include any manufacturer of any authorized generic drug(s) and any repackager or relabeler of the selected drug that meet these criteria. A manufacturer that is not listed as a manufacturer on the NDA / BLA and without an agreement in place with the Primary Manufacturer would not be considered a Secondary Manufacturer.

- Sections 1 through 5 in this ICR Form include references to Sections C through G of the forthcoming Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (CMS-10844, OMB 0938-1452) (the "Drug Price Negotiation ICR"), which CMS intends to publish for a 60-day public comment period in Summer 2025.[15]
- Instructions within each of Sections 1 through 5 of this ICR Form specify the applicable reporting time period for the section.
  - If a Primary Manufacturer has new updates to the original statutorily-required submission of 1194(e)(1) data, the Primary Manufacturer should notify CMS of these updates separately from this ICR Form in accordance with section 50.1 of the revised guidance for initial price applicability year 2026 and the final guidance for initial price applicability year 2027.

Instructions for Reporting Monetary Amounts

- When calculating and reporting monetary values, the information should be determined using the methodologies described throughout the document and consistent with the Generally Accepted Accounting Principles (GAAP), when applicable. Describe the policies and methodologies used in the calculations in the free response field for the relevant question, as well as the standard used if it is inconsistent with GAAP.
- When calculating and reporting monetary values, do not adjust responses for cost of capital.
- Monetary amounts must be reported in United States dollars (USD) and include two decimal places (i.e., dollars and cents), unless otherwise specified. Use the free response field of an applicable question, when it is available, to clarify any rounding limitations or alternative rounding standard relied on.
- The geographic area for data on U.S. Commercial markets, Medicare markets, and Medicaid markets is based on the definition of the United States in 42 C.F.R § 400.200, unless the geographic area is specified in the authority for the data source.
- When converting another currency to USD, specify in the free response field of the applicable question which of the following options were used:
  1. the exchange rate applicable at the time the costs were incurred. The Internal Revenue Service (IRS) website lists government and external sources where historical exchange rates can be found to the day.[16] If the exact date of a sale or conversion is not known, use the yearly average exchange rate for that currency for the year the costs were incurred.[17] In the free response field, report the amount, the currency, the exchange rate, and time period(s) used in this calculation, or
  2. the GAAP Accounting Standard Certification (ASC) 830 for translating foreign currencies.
- Do not report the same costs in multiple places unless the additional specific instructions for

[15] Previous versions of the Drug Price Negotiation ICR (CMS-10844, OMB 0938-1452) approved by OMB are available on OMB's website at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202411-0938-010 and are collectively referred to as the Drug Price Negotiation ICR in this ICR Form.
[16] See: https://www.irs.gov/individuals/international-taxpayers/foreign-currency-and-currency-exchange-rates.
[17] See: https://www.irs.gov/individuals/international-taxpayers/yearly-average-currency-exchange-rates.

that question instruct you to do so.

- Do not include any costs that are unallowable under an applicable law or costs that are otherwise expressly excluded from this ICR Form.
- Do not make any adjustments for inflation to any dollar amounts reported unless the additional specific instructions for that question instruct you to do so. When reporting an inflation adjusted value, inflate to the most recent calendar year prior to the submission of this ICR Form. For example, for drugs selected in initial price applicability year 2028 where data is submitted in calendar year 2026, inflation adjustments should be made to 2025.

Section 1: Research and Development (R&D) Costs and Recoupment *(Section C of the Drug Price Negotiation ICR)*

This section contains three data questions related to global research and development (R&D) costs incurred by the Primary Manufacturer related to the selected drug and global and U.S. net revenue for CMS' consideration of the extent to which R&D costs have been recouped by the Primary Manufacturer related to the selected drug.

Definitions for Section 1:

R&D costs mean a combination of costs incurred by the Primary Manufacturer for indications[18] of a drug falling into the two categories below, and excluding the following: (a) prior Federal financial support and (b) costs associated with applying for and receiving foreign approvals:

- R&D: Costs Related to the Selected Drug, Including Basic Pre-Clinical Research for Indications of the Selected Drug, Post-IND Costs for Indications of the Selected Drug and Other Allowable Costs
- R&D: Costs for Failed and Abandoned Products Related to the Selected Drug

CMS is including both the global and U.S. net revenue for the selected drug in its consideration of the extent to which the Primary Manufacturer has recouped R&D costs.

- Recoupment: Global and U.S. Net Revenue for the Selected Drug

The definitions and associated time periods for these terms are included below.

Instructions for Questions 1 through 3:

- For each dollar amount listed below, the Primary Manufacturer may report one dollar amount in the numerical response field. If a dollar amount is provided, the Primary Manufacturer must provide an explanation of the value(s), including any calculations or conversions and any assumptions made in the free response field.
  - All dollar figures submitted to CMS must be cash-outlay costs to the Primary Manufacturer. They must exclude any costs to entities that are not the Primary Manufacturer.

[18] For purposes of this ICR and the Negotiation Data Elements and Drug Price Negotiation Process ICR, CMS distinguishes between the use of the word "indication" and the term "FDA-approved indication" such that "FDA-approved indication" refers to the information included in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s), and "indication" refers to the condition or disease state for which the selected drug is used.

- Reported R&D costs are allowable for the following applicable time periods:
  - R&D costs meeting the definitions below that were incurred after the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated through September 30, 2025; and
  - R&D costs meeting the definitions below for **new FDA-approved indications** with the date of FDA approval for the new indication occurring on or after the date the Primary Manufacturer was statutorily-required to certify the Primary Manufacturer's original full submission (hereinafter, referred to as the "date of certification of the Primary Manufacturer's original full submission").[19] For a new FDA-approved indication, a Primary Manufacturer may report applicable: (1) direct and proportion of indirect costs for basic pre-clinical research, (2) direct post-IND costs, and (3) direct costs on other allowable costs from the date of initial discovery *or* the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug (whichever is later) through September 30, 2025.
    - The Primary Manufacturer may only report costs with respect to a new FDA-approved indication if those R&D costs were not already reported in the prior submission.
- Global and U.S. net revenue incurred for the selected drug must be reported from the last date for which data was reported for net revenue in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated through September 30, 2025.
- For Questions 1 through 3, if R&D costs and/or net revenue for the selected drug are not available for the exact dates specified above in these instructions, the R&D costs and/or net revenue may be reported through the most recent quarter for which such data are available. The Primary Manufacturer should specify the time period used in the free response field for each question.
- If the Primary Manufacturer received any prior Federal financial support, as defined in Section 3 in this ICR *(Section E in the Drug Price Negotiation ICR)*, for any of the costs listed in Questions 1 through 2 below (e.g., basic pre-clinical research, clinical trials, etc.), deduct such funding from the final calculated numerical amount before answering the relevant question and note that deduction in the applicable free response field. CMS will be collecting additional information on prior Federal financial support in Questions 6, 7, and 8. Please reference Section 3 *(Section E of the Drug Price Negotiation ICR Form)* for instructions on reporting prior Federal financial support.
- If the Primary Manufacturer shared the expenses described in Questions 1 through 2 (after any acquisition of the selected drug, if relevant) for any period of time or activity with any entity that is not the Primary Manufacturer, then the Primary Manufacturer must report only costs the Primary Manufacturer incurred. Report how shared expenses were allocated among the Primary Manufacturer and any other entity or entities in the free response field for the relevant question.
- Follow the instructions for Reporting Monetary Amounts, including those related to converting to USD if R&D costs occurred in other countries. While R&D may occur in other

[19] For a drug selected for initial price applicability year 2026, the statutory deadline for submission of the section 1194(e)(1) data was October 2, 2023. For a drug selected for initial price applicability year 2027, the statutory deadline was March 1, 2025.

countries and those costs may be included and reported in USD, costs associated with applying for and receiving foreign approvals must not be included.
- Acquisition costs are not allowable in Section 1 in this ICR.

Definitions for Section 1:
- Post-IND costs are defined as direct costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials for each FDA-approved indication. Post-IND costs also include direct costs associated with completed FDA-required, postmarketing trials that are conducted after the FDA has approved a product.
- Direct post-IND costs are defined as Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel (compensation for investigators and staff) researching the selected drug, and facility costs that are directly related to conducting the dosing and Phase I, Phase II, and Phase III clinical trials during the post-IND period. Direct post-IND costs also include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the completed FDA-required, postmarketing trial.
- Personnel, patient recruitment, and per-patient costs include monetary and non-monetary compensation. Any non-monetary compensation for investigators and staff included in the total amount should reflect the fair market value for such compensation at the time it was provided.

Question 1: Costs Related to the Selected Drug, Including New Basic Pre-Clinical Research for Indications of the Selected Drug, Post-IND Costs for Indications of the Selected Drug and Other Allowable Costs

Provide the following information about R&D costs (for the time periods as specified in the instructions above) incurred by the Primary Manufacturer for indications for the selected drug related to basic pre-clinical research, post-IND costs for the selected drug, and other allowable costs, as described in more detail below.

Additional Definitions for Question 1:

R&D: Basic Pre-Clinical Research Costs Related to the Selected Drug
- Basic pre-clinical research costs are the sum of (1) direct research expenses; and (2) the appropriate proportion of indirect research expenses (defined below).
- Direct basic pre-clinical research costs are costs that can be specifically attributed to the discovery and pre-clinical development of the selected drug. Direct research expenses could include personnel (monetary and non-monetary compensation for investigators and staff) researching the selected drug, materials for conducting basic pre-clinical research, and the costs of in vivo and in vitro studies on the selected drug before an IND application went into effect.
- Indirect basic pre-clinical research costs and relevant general and administrative expenses are operating costs for basic pre-clinical research beyond the basic pre-clinical research costs for the selected drug, including administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biological

products.

Other Allowable Costs:

- Other allowable costs for all costs related to the selected drug are defined as direct costs associated with conducting FDA-required postmarketing trials and other FDA post-marketing requirements and commitments that were not completed, direct costs associated with Phase IV postmarketing studies for FDA-approved indications that were not required by FDA, direct post-IND costs for indications that did not receive FDA approval (following the definitions and instructions for calculating direct post-IND costs above), direct costs associated with researching and utilizing devices for the selected drug, and direct costs associated with generating real-world evidence that was submitted to FDA to support the safety or effectiveness of a selected drug and direct costs to support or satisfy a postmarketing requirement or commitment.
- Direct costs for other allowable costs include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting Phase IV and postmarketing trials.

Instructions for Question 1a:

- In the numerical response field, report the sum of the *new* (1) direct and proportion of indirect costs for basic pre-clinical research for the selected drug, (2) direct post-IND costs, and (3) direct costs on other allowable costs.
- Do not make adjustments for inflation or for the cost of capital.
- To calculate the proportion of pre-clinical indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is used to estimate the proportional spending for indirect research.[20],[21] For example, if the *direct* pre-clinical research costs spent on the selected drug were approximately 10 percent of a Primary Manufacturer's total *direct* basic pre-clinical research costs for that period of time, then *indirect* costs should be allocated proportionally. Thus, for the selected drug, they should be 10 percent of the total spending on *indirect* pre-clinical research costs during that time period.

FIELD	**RESPONSE FORMAT**
Costs Related to the Selected Drug	$

Instructions for Question 1b:

- List the direct and indirect costs for the selected drug that were included in the reported amount in Question 1a.

[20] Wouters OJ, McKee M, Luyten J., Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA.* 2020;323(9):844–853. doi:10.1001/jama.2020.1166.

[21] Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL., *Methods for the Economic Evaluation of Health Care Programme*. 3rd ed. Oxford, UK: Oxford University Press, 2005, see https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html.

FIELD	RESPONSE FORMAT
List of the direct and indirect costs for the selected drug included in Question 1a	*Text (6,000 character count limit, which is approximately 500 words)*

Instructions for Question 1c:

- Explain how the numerical value reported in Question 1a was calculated, including the allocation and apportionment methods. This explanation should include whether any of the reported costs are associated with a new indication(s) and the total costs that are attributable to the new indication(s). If there are multiple new indications, please differentiate costs by indication, where applicable.
- Report the cost included in the response to Question 1a adjusted for inflation, and explain any methodology relevant to this reported amount.

FIELD	RESPONSE FORMAT
Explanation of Costs Related to the Selected Drug, Including Allocation and Apportionment Methods, and an Inflation Adjusted Value with an Explanation of the Methodology for the Inflation Adjustment	*Text (30,000 character count limit, which is approximately 2,500 words)*

Question 2: Costs of Failed or Abandoned Products Related to the Selected Drug

The Primary Manufacturer may report *direct* costs spent on basic pre-clinical research and clinical research for failed or abandoned products that are directly attributable to the selected drug (for the time periods as specified in the instructions above).

Additional Definitions for Question 2:
R&D: Costs of Failed or Abandoned Products Related to the Selected Drug

- Failed or abandoned product costs include direct *basic pre-clinical research* costs on drugs with the same mechanism of action as the selected drug that did not make it to clinical trials.
  - Direct research expenses are costs that can specifically be attributed to the discovery and pre-clinical development of the drug.
  - Direct research expenses include personnel (monetary and non-monetary compensation for investigators and staff) researching the drug, materials for conducting basic pre-clinical research, and in vivo and in vitro studies on the drug.
- Failed or abandoned products costs include direct *post-IND costs* for drugs with the same mechanism of action as the selected drug that did not receive FDA approval.
  - Direct post-IND costs are costs that can specifically be attributed to the dosing and clinical trials for the drug.
- Acquisition costs for failed or abandoned products are not allowable.

Instructions for Question 2a:

- In the numerical response field, only include basic pre-clinical research or post-IND costs that can be directly attributed to failed or abandoned product(s) with the same mechanism of action as the selected drug that did not receive FDA approval.

FIELD	RESPONSE FORMAT
Costs of Allowable Failed or Abandoned Products Related to the Selected Drug	*$*

Instructions for Question 2b:

- List all the applicable direct costs included in the numerical value given in Question 2a.

FIELD	RESPONSE FORMAT
List of the direct costs included in this question	*Text (6,000 character count limit, which is approximately 500 words)*

Instructions for Question 2c:

- In the free response field, detail how these costs were determined, what portion of direct costs was included for basic pre-clinical research and direct post-IND costs, and how any allocation was done.
- Report the cost included in response to Question 2a adjusted for inflation, and explain any methodology relevant to this reported amount.

FIELD	RESPONSE FORMAT
Explanation of Costs on Allowable Failed or Abandoned Products Related to the Selected Drug, Including Allocation and Apportionment Methods, and an Inflation Adjusted Value with an Explanation of the Methodology for the Inflation Adjustment	*Text (30,000 character count limit, which is approximately 2,500 words)*

Question 3: Global and U.S. Net Revenue for the Selected Drug

CMS will use both the Primary Manufacturer's global and U.S. net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug (for the time periods as specified in the instructions above).

Definitions for Question 3a: Global, including U.S., Net Revenue for the Selected Drug:

- Global net revenue for the selected drug is defined as the direct sales and payments from all other entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in-kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.

FIELD	RESPONSE FORMAT
Global Net Revenue for the Selected Drug	*$*

- In the free response field, explain how the final global net revenue was calculated, including any relevant currency conversions.
- Report the net revenue included in response to Question 3a adjusted for inflation, and explain any methodology relevant to this reported value.

FIELD	RESPONSE FORMAT
Explanation of Global Net Revenue for the Selected Drug and an Inflation Adjusted Value with an Explanation of the Methodology for the Inflation Adjustment	*Text (30,000 character count limit, which is approximately 2,500 words)*

Definitions for Question 3b: U.S. Net Revenue for the Selected Drug**:**

- U.S. net revenue for the selected drug is defined as the direct sales and payments from U.S. entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.

FIELD	RESPONSE FORMAT
U.S. Net Revenue for the Selected Drug	*$*

- In the free response field, explain how the U.S. net revenue was calculated.
- Report the net revenue included in response to Question 3b adjusted for inflation, and explain any methodology relevant to this reported value.

FIELD	RESPONSE FORMAT
Explanation of U.S. Net Revenue for the Selected Drug and an Inflation Adjusted Value with an Explanation of the Methodology for the Inflation Adjustment	*Text (30,000 character count limit, which is approximately 2,500 words)*

Section 2: Current Unit Costs of Production and Distribution *(Section D of the Drug Price Negotiation ICR)*

This section contains two questions on current unit costs of production and distribution for the selected drug (for the time period as specified in the instructions below). Question 4 is a table in which to report the average unit costs of production and distribution for each NDC-11 of the selected drug. Question 5 provides a free response field for explaining the methodology for calculating the amount reported in Question 4.

Definitions:

- In accordance with section 1191(c)(6) of the Act, the term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (e.g., capsule or tablet, milligram of molecules, grams, international units) of the drug or biological product that is dispensed or furnished.
- Units must be reported in one of the three National Council for Prescription Drug Programs

(NCPDP) Billing Unit Standard (BUS)[22]. The three NCPDP BUS are: each (EA), milliliter (ML), and gram (GM). For certain volume data of the selected drug, CMS is requesting units be reported using the NCPDP BUS to facilitate comparison with the amounts in the quantity dispensed field found in PDE data, which also uses the NCPDP BUS.

- Costs of production are defined as all (direct and allocation of indirect) costs related to:
  - Purchase of raw ingredients, including intermediates, active pharmaceutical ingredients, excipients, and other bulk chemicals;
  - Formulation and preparation of the finished drug product;
  - Quality control and testing of the drug; and
  - Operating costs for personnel, facilities, transportation, importation (if any), and other expenses related to the preparation of the finished drug product for the selected drug.
- Costs of distribution are defined as all (direct and allocation of indirect) costs related to:
  - Packaging and packaging materials;
  - Labeling (e.g., the mechanical aspects of printing and affixing the approved label);
  - Shipping to any entity (e.g., distributor, wholesaler, retail or specialty pharmacy, physician office or hospital, etc.) that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer; and
  - Operating costs for facilities, transportation, and other expenses related to packaging, labeling, and shipping to any entity that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer.
- Current unit costs of production and distribution of the selected drug are defined to include:
  - Units (and associated costs) marketed by the Primary Manufacturer and any Secondary Manufacturer(s);
  - Only units (and associated costs) produced and distributed for U.S. sales; costs incurred outside of the U.S. are included, provided that they are incurred for the production or distribution of units produced and distributed for use in the U.S.;
  - Only costs incurred by the Primary Manufacturer and any Secondary Manufacturers; such costs may include payments to third-party vendors (e.g., contractors) performing activities that qualify as production or distribution, as specified above; and
  - Allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses) specific to each NDC-11 based on unit volume.
- Current unit costs of production and distribution of the selected drug do not to include:
  - R&D costs;
  - Marketing costs; and
  - Transfer prices.
- "Marketing costs" are defined as expenditures incurred in the introduction or delivery for introduction into interstate commerce of a drug product, specifically including media advertisements, direct-to-consumer promotional incentives including patient assistance programs, promotion of the drug to health professionals, including providing free products to health professionals or patients, and other paid promotion.
- "Transfer prices" are defined as prices charged for goods, services, or other intangible assets in transactions between two members of the same controlled group of the Primary

[22] See: NCPDP BUS: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

Manufacturer or any Secondary Manufacturer, including sales of a drug product, provision of services (e.g., contract manufacturing), or transfer of intellectual property. For the purposes of the definition of transfer prices, "controlled group" of the Primary Manufacturer or any Secondary Manufacturer refers to all entities that were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code and the Department of the Treasury regulations thereunder.

Instructions:

Follow the instructions below when answering Questions 4 and 5:

- Production and distribution unit costs must be reported separately for each NDC-11 of the selected drug, including any NDC-11 of the selected drug marketed by a Secondary Manufacturer.
- Unit costs reported must represent the average per unit cost (1) within the time period specified below, (2) across all package types, and (3) calculated according to the instructions and using the definitions specified below.
- Use the response field in Question 5 to explain any shared operating and other indirect costs that were included in the response to Question 4.
- Costs may be reported up to three decimal places (USD).

Question 4: Per Unit Production and Distribution Costs

Please complete the following table using additional rows as necessary for the following periods:

- for a drug that was selected for negotiation for initial price applicability year 2026, for the 12-month period ending September 30, 2025, and
- for a drug that was selected for negotiation for initial price applicability year 2027, for the 9--month period ending September 30, 2025.

NDC-11	Average Per Unit Production Cost	Average Per Unit Distribution Costs	NCPDP Unit (EA, ML, GM)	Total Unit Volume	Costs are Not Available	Explanation of Why Costs are Not Available
12345-6789-01	*$XX.XXX*	*$XX.XXX*	*Text*	*#*	*Select if applicable*	*Text (30,000 character count limit, which is approximately 2,500 words)*

Question 5: Explanation of Calculation of Per Unit Production and Distribution Costs

Please describe the methodology used to calculate the average per unit costs of production and distribution reported in Question 4, including which indirect costs were included, specific allocation methodologies, assumptions, and whether such assumptions apply to all or a subset of the data reported.

Specifically, include any assumptions about costs including but not limited to:

- Allocated general and administrative overhead;
- Cost of capital;
- Labor compensation;
- Any included costs that were incurred outside of the U.S.;
- Allocated shared facility costs;
- Allocated shared transportation or other operational costs;
- Depreciation of facilities, equipment, or other assets involved in the production and distribution of the selected drug; and
- Number of units of drug samples and how their cost was determined.

FIELD	**RESPONSE FORMAT**
Explanation of Unit Production and Distribution Costs	*Text (30,000 character count limit, which is approximately 2,500 words)*

Section 3: Prior Federal Financial Support *(Section E of the Drug Price Negotiation ICR)*

This section focuses on capturing Federal financial support incurred for novel therapeutic discovery and development with respect to the selected drug (for the time periods as specified in the instructions below).

Definitions:

- "Federal financial support for novel therapeutic discovery and development" refers to tax credits, direct financial support, grants or contracts, in-kind contributions (e.g., support in the form of office/laboratory space or equipment), and any other funds provided by the federal government that support discovery, research, and/or development related to the selected drug.
- Prior Federal financial support includes the manufacturer's reasonable estimate of the dollar value of in-kind contributions and Cooperative Research and Development Agreements (CRADAs) that do not have a readily ascertainable value.
- Direct prior federal financial support costs are costs that can be specifically attributed to the discovery, pre-clinical development, and clinical trials of indications of the selected drug.

Instructions:

Follow the instructions below when answering Questions 6, 7, and 8:

- Include prior Federal financial support provided by U.S. federal agencies or Federally-supported grants or contracts that contributed to direct costs for the basic pre-clinical research and clinical trials phase of research and development for indications of the selected drug to the Primary Manufacturer only (do not include Federal financial support provided to applicable Secondary Manufacturers of a selected drug) that was issued during the time period from the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated through September 30, 2025.
  - If a new indication was added since the date of certification of the Primary Manufacturer's original full submission of section 1194(e) data, include all applicable prior Federal financial support for that new indication from when

initial research began (as defined above in the R&D Costs subsection (which is Section 1)), or when the drug was acquired by the Primary Manufacturer, whichever is later, through September 30, 2025.

- For Question 6, if prior Federal financial support for the selected drug is not available for the exact dates specified above in these instructions, the prior Federal financial support may be reported through the most recent quarter for which such data are available. The Primary Manufacturer should specify the time period used in Question 7.
- Include new prior Federal financial support received for indirect costs of developing the selected drug. These indirect costs are operating costs such as administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biological products.
  - To calculate the proportion of indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is used to estimate the proportional spending for indirect research.[23], [24] For example, if the *direct* costs spent on the selected drug were approximately 10 percent of a Primary Manufacturer's total *direct* basic pre-clinical research costs, then *indirect* costs must be allocated proportionally, thus for the selected drug they must be 10 percent of the total spending on *indirect* costs during that time period.
  - For grants, Primary Manufacturers should use the indirect cost rate at the time of data submission to calculate the proportion of funds that should be allocated to indirect costs. This indirect cost rate could be the fixed rate, provisional/final rate, or predetermined rate.
  - For in-kind contributions and CRADAs, if the dollar value of the in-kind contribution or CRADA is not readily ascertainable, the recipient should provide a reasonable estimate.
- If the Primary Manufacturer received new prior Federal financial support for a failed or abandoned product with the same mechanism of action as the selected drug that did not make it to clinical trials and/or drugs with the same mechanism of action as the selected drug that did not receive FDA approval, including indications for the selected drug that did not receive approval, the Primary Manufacturer should not include this amount in its answer for Question 6. Instead, the Primary Manufacturer must include this amount as a separate quantity when explaining prior Federal financial support in Question 7.
- If the Primary Manufacturer shared the prior Federal financial support described in Questions 6 through 8 for any period of time or activity with any entity that is not the Primary Manufacturer, then the Primary Manufacturer must report support received only for costs the Primary Manufacturer incurred. Expenses should be allocated across entities based on each entity's respective stake in the selected drug's discovery and development. The allocation to the Primary Manufacturer should be reported as a dollar amount and the percentage of the total amount allocated to the Primary Manufacturer should be included in the free response

[23] Wouters OJ, McKee M, Luyten J., Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA.* 2020;323(9):844–853. doi:10.1001/jama.2020.1166.
[24] Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL., *Methods for the Economic Evaluation of Health Care Programme*. 3rd ed. Oxford, UK: Oxford University Press, 2005, https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html.

field in Question 8. For example, if the Primary Manufacturer was allocated 80 percent of the prior Federal financial support for a period of the selected drug's development, the Primary Manufacturer would include 80 percent of that support in its total number for prior Federal financial support in Question 6. Then, it would note the source of the shared prior Federal financial support and that it received 80 percent of that support in Question 7. If the shared support came in the form of an agreement, the Primary Manufacturer would include this in the "Nature of Agreement" section of Question 8.

Question 6: Federal Funding Support Amount

Complete the table below. Do not make adjustments for inflation.

FIELD	RESPONSE FORMAT
Total Federal Financial Support	$

Question 7: Explanation of Calculation of Federal Financial Support

Disaggregate the total Federal financial support amount reported above by the amounts allocated to the sources in the list below. Please list amounts in order of highest to lowest. In addition, describe assumptions, methodological steps, and other information needed to calculate the estimates provided in Question 6. If you report a value for "other Federal financial support not otherwise included elsewhere" in your response to this question, please list the source(s) of that Federal financial support. Please include the identification number for grants and comparable awards.

- Tax credits (General, R&D)
- Orphan Drug Act and other specific tax credits
- National Institutes of Health (NIH) funding
- Department of Defense (DOD) Congressionally Directed Medical Research (CDMR) funding
- Biomedical Advanced Research and Development Authority (BARDA) funding
- Defense Advanced Research Projects Agency (DARPA) funding
- Federal financial support for failed or abandoned indications for the selected drug
- Federal financial support for failed or abandoned products related to the selected drug (as described in the definitions for this section)
- CRADA support
- In-kind contributions not included elsewhere
- Other Federal financial support not included elsewhere

FIELD	RESPONSE FORMAT
Federal Financial Support	*Text (36,000 character count limit, which is approximately 3,000 words)*

Report each total Federal financial support disaggregated amount adjusted for inflation, and explain the methodology used to adjust for inflation.

FIELD	RESPONSE FORMAT
Federal Financial Support disaggregated amount adjusted for inflation	*Text (36,000 character count limit, which is approximately 3,000 words)*
Explanation of methodology used to adjust for inflation	*Text (6,000 character count limit, which is approximately 500 words)*

Question 8: Agreements Between Primary Manufacturer and Federal Government

List and describe any new licensing agreement, pricing agreement, purchasing agreement, and other agreements in place between your company and any federal government agency related to the discovery, research, and/or development of the selected drug if the agreement was not finalized or in effect as of the date of the statutorily required certification of the Primary Manufacturer's original full submission. Add additional rows to your response to Question 8 as needed.

- In the "Nature of Agreement" field, please provide details on the terms of the agreement, such as information on pricing, the nature and amount of goods/services agreed upon, an explanation of the allocation methodology to the selected drug, timelines to delivering goods/services, conditions on the agreement (exclusivity, sole supplier, etc.) and effective dates and expiration dates, if applicable. For example, this field could detail an agreement between the Primary Manufacturer and Federal Government where the Primary Manufacturer agrees to produce a certain quantity of a drug that is being developed and has not yet been approved or licensed, deliver it to the Federal Government within a specified timeline, and not contract with other state or local governmental entities or insurers while this agreement is in place.

Type of Agreement	Federal Agency(ies) Participating in Agreement	Nature of Agreement
Select the agreement option: licensing, pricing, purchasing, other, none	*Text (1,200 character count limit, which is approximately 100 words)*	*Text (12,000 character count limit, which is approximately 1,000 words)*

Section 4: Patents and Exclusivities *(Section F of the Drug Price Negotiation ICR)*

This section focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications under section 505(c) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act) or section 351(a) of the Public Health Service ("PHS Act") (for the time periods as specified in the instructions below).

Follow the instructions below when answering Questions 9 through 11.

Definitions:

- Patents Exclusivities and Approvals. CMS considers relevant patents, both expired and unexpired, and relevant patent applications to include:

- All patents issued by the United States Patent and Trademark Office (USPTO), both expired and unexpired, for which a claim of patent infringement could reasonably be, or has been, asserted against a person or manufacturer engaged in the unlicensed manufacture, use, or sale of the selected drug in any form or any person or manufacturer seeking FDA approval of a product that references the selected drug.
    - All patents relevant to the selected drug, both expired and unexpired, where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product or if any patents related to the selected drug are held by a federal agency).
    - All patent applications related to the selected drug that are pending issuance by the USPTO.
- Patents and patent applications relevant to the selected drug include, but are not limited to, any patents that are, have been, or may be listed for the selected drug in the FDA Orange Book or Purple Book;[25] patents that claim the drug product (e.g., the final product taken by or administered to a patient), drug substance (active ingredient) or other chemicals related to the active ingredient of a selected drug (e.g., crystalline forms, polymorphs, salts, metabolites, or intermediates); patents that claim a formulation of the drug; method-of-use patents (e.g., patents that claim an indication or use of the drug for treating a particular disease); process patents (e.g., patents that claim technologies and method(s) of manufacturing the drug); device patents (e.g., patents that claim the device used to administer the selected drug); and design patents (e.g., patents that claim a design on the packaging of the selected drug).
- Relevant patents and patent applications do not include patent applications that were denied by the USPTO.
- Exclusivity periods under the FD&C Act or the PHS Act refer to certain delays on the submission or approval of applications for competitor drug products. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met. Exclusivities include:
    - Orphan Drug Exclusivity (ODE);[26]
    - New Chemical Entity Exclusivity (NCE);[27]
    - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);[28]
    - New Clinical Investigation Exclusivity (NCI);[29]
    - Pediatric Exclusivity (PED);[30] and
    - Reference Product Exclusivity for Biological Products.[31]
- Active and pending FDA applications and approvals include all applications for approval under section 505(c) of the FD&C Act or section 351(a) of the PHS Act, including those not yet decided.

[25] FDA serves a ministerial role with regard to the listing of patent information in the Orange Book and Purple Book.
[26] Section 527 of the FD&C Act.
[27] Section 505(c)(3)(E)(ii) and Section 505(j)(5)(F)(ii) of the FD&C Act.
[28] Section 505E(a) of the FD&C Act.
[29] Section 505(c)(3)(E)(iii) & (iv) and Section 505(j)(5)(F)(iii) & (iv) of the FD&C Act.
[30] Section 505A(b) & (c) of the FD&C Act.
[31] Section 351(k)(7) of the PHS Act.

Instructions:
For Questions 9 through 11, the relevant time period for reporting is:

- for a drug selected that was selected for negotiation for initial price applicability year 2026, include patents and exclusivities issued after September 1, 2023 through September 30, 2025; and
- for a drug selected that was selected for negotiation for initial price applicability year 2027, include patents and exclusivities issued after February 1, 2025 through September 30, 2025.

Question 9A: Patents (Expired and Non-Expired)

In the table below, please list each patent that is relevant to the selected drug for the applicable time period specified in the instructions. As noted at the beginning of this ICR form, do not report relevant patents included in the Primary Manufacturer's original full submission of section 1194(e)(1) data.

If you are reporting a new approved patent that was not previously included on this list in your prior submission, for each such patent (expired or unexpired) listed in the table below, in the patent explanation field, please provide a clear and concise written description of the patented invention and, if relevant, of the manner and process of making and using the invention, as well as how a patent relates to any other patents listed in the table. For example, if a listed patent is a parent or child of another patent, include the patent number and how the two patents relate to each other. Clearly identify which patent or patents is the composition of matter patent(s) in the free response. If the patent was previously listed in the FDA Orange Book or Purple Book but is no longer listed, please explain why.

A Zip file of the USPTO patent application(s) may be uploaded but is not required for this question 9A. Add additional rows to your response to Question 9A as needed.

Patent Number	**Date Filed**	**Patent Expiry Date**	**Patent Type**	**Never, Previously, or Currently Listed in FDA Orange Book/Purple Book**	**Patent Explanation**	**Patent Application**
#	*MM/ DD/ YYYY (not applicable it patent expired)*	*MM/ DD/ YYYY*	*Select patent type (allow more than one to be selected): drug product patent; drug*	*Never/ Previously/ Currently*	*Text (3,600 character count limit, which is approximately 300 words*	*Optional. Upload corresponding patent application*

Patent Number	Date Filed	Patent Expiry Date	Patent Type	Never, Previously, or Currently Listed in FDA Orange Book/Purple Book	Patent Explanation	Patent Application
			substance patent; formulation patent; process patent; method-of-use patent; device patent; other (e.g., patent that claims other chemicals related to the active ingredient, design patent)			

Question 9B: Patent Applications

In the data fields below, please list each patent application that is relevant to the selected drug for the applicable time period specified in the instructions. As noted at the beginning of this ICR form, do not report relevant patent applications included in the original full submission of the section 1194(e)(1) data.

For each patent application listed in the table below, in the patent explanation field, please provide a clear and concise written description of the invention and, if relevant, of the manner and process of making and using the invention, as well as how a patent application relates to any other patents if you are reporting a new patent that was not previously included on this list in your prior submission. Do not include patent applications that were denied.

Please upload a Zip file of a PDF file of the USPTO patent application. Add additional rows to your response to Question 9B as needed.

Patent Number	Date Filed	Patent Type	Patent Explanation	Patent Application
#	MM/ DD/ YY YY	Select patent type (allow more than one to be selected): drug product patent; drug substance patent; formulation patent; process patent; method-of-use patent; device patent; other (e.g., patent that claims other chemicals related to the active ingredient, design patent)	Text (3,600 character count limit, which is approximately 300 words)	Upload corresponding patent application.

Question 10: Exclusivity Periods

As applicable, please report all exclusivity periods under the FD&C Act or the PHS Act that are listed or were listed in the Orange Book or the Purple Book and are in effect or have expired for the selected drug for the applicable time period specified in the instructions. Do not report exclusivity periods listed in the Primary Manufacturer's original full submission of section 1194(e)(1) data.

Complete table for Question 10 by adding rows as needed.

Type of Exclusivity	Exclusivity Expiration Date	Application (NDA / BLA) Number	NDC-9s Covered by Exclusivity	Comments
Select exclusivity type: Orphan Drug Exclusivity, New Chemical Entity Exclusivity, Generating Antibiotic Incentives Now Exclusivity for Qualified Infectious Disease Products, New Clinical Investigation Exclusivity, Pediatric Exclusivity, Reference Product Exclusivity for Biological Products	MM/DD/YY YY	#	Text	Text (3,600 character count limit, which is approximately 300 words)

Question 11: All Active and Pending FDA Applications

List all active and pending FDA applications for the selected drug under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the applicable time period specified in the instructions. Do not report active or pending FDA applications listed in the Primary Manufacturer's original full submission of section 1194(e)(1) data. *Complete table for Question 11 by adding rows as needed using the indicated format.*

Please submit any efficacy supplements that are pending FDA approval but exclude manufacturing supplements for the applicable time period specified in the instructions.

Application (NDA / BLA) Number	**Application Type (NDA; BLA)**	**Classification Code**[32]	**Indication**	**Dosage Form and Strength**	**Sponsor**	**Application Status**	**Comments**
#	*Select the application type: NDA, BLA*	Select one or more of the following options: Options: Type 1 — New Molecular Entity, Type 2 — New Active Ingredient, Type 3 — New Dosage Form, Type 4 — New Combination, Type 5 — New Formulation or Other Differences (e.g., new indication, new applicant, new manufacturer), Type 6 — New Indication or Claim, Same Applicant, Type 7 — Previously Marketed But Without an Approved NDA, Type 8 — Rx to OTC, Type 9 New Indication or	*Text*	*Text*	*Text*	*Select one of the following options: tentatively approved, pending, withdrawn, or other*	*Text (3,600 character count limit, which is approximately 300 words)*

[32] These classification code options apply only to the "NDA" application type. BLAs do not use classification codes.

Application (NDA / BLA) Number	Application Type (NDA; BLA)	Classification Code[32]	Indication	Dosage Form and Strength	Sponsor	Application Status	Comments
		Claim, Drug Not to be Marketed Under Type 9 NDA After Approval, Type 10 — New Indication or Claim, Drug to be Marketed Under Type 10 NDA After Approval					

Section 5: Market Data and Revenue and Sales Volume Data *(Section G of the Drug Price Negotiation ICR)*

The purpose of Questions 12 and 13 in this section is to collect the market data and revenue and sales volume data described in section 1194(e)(1)(E) of the Act.

Definitions:

- The three NCPDP BUS[33] are: each (EA), milliliter (ML), and gram (GM). For certain volume data of the selected drug, CMS is requesting units be reported using the NCPDP BUS for all but Medicaid best price to facilitate comparison with the amounts in the quantity dispensed field found in PDE data, which also uses the NCPDP BUS.
- Manufacturer U.S. commercial average net unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for group or individual commercial plans on- and off-Exchange, excluding Medicare fee-for-service (Part A and Part B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care. The following items should be deducted from gross revenue in your calculation: discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The following items should not be deducted from gross revenue in your calculation: manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary

[33] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

Manufacturer(s). The U.S. commercial average net unit price is reported at the NDC-11 level.

- Manufacturer U.S. commercial average net unit price– net of patient assistance program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the following items should be deducted from the gross revenue in your calculations: manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The following items should not be deducted from gross revenue in your calculations: discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price– net of patient assistance program is reported at the NDC-11 level.
- Manufacturer U.S. commercial average net unit price– best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest U.S. commercial average net unit price offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer in the U.S. The following items should be deducted from gross revenue in your calculations: discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced- price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer or any Secondary Manufacturer(s) to any purchasers. The following items should not be deducted from the gross revenue in your calculations: manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price – best is reported at the NDC-11 level.

Instructions:

- For Questions 12 and 13, information for the Primary Manufacturer and any Secondary Manufacturer(s) must be reported.
- For Question 12, for the sole purpose of data collection under section 1194(e)(1)(E) of the Act, as applicable, the total unit volume must be reported at the NDC-11 level and reflect the NCPDP BUS. The total unit volume must include the total unit volume sold by the Primary Manufacturer and any Secondary Manufacturer(s) in the U.S. for the data reported.

Question 12: Manufacturer U.S. Commercial Average Net Unit Price

Follow the instructions below when providing responses in the following table about the Manufacturer U.S. commercial average net unit price, including group and individual commercial plans on- and off-Exchange of the selected drug:

- For each NDC-11, that is included in the Primary Manufacturer's NDC-11s in the "Manage NDC-11s" module in the CMS HPMS, include the following:
  - for a drug that was selected for negotiation for initial price applicability year 2026, a row for each calendar quarter in calendar years 2023, 2024, and a row for each calendar quarter in calendar year 2025 through the calendar quarter ending with September 30, 2025, and

- for a drug that was selected for negotiation for initial price applicability year 2027, a row for each calendar quarter in calendar year 2025 through the calendar quarter ending with September 30, 2025.

- If the NDC-11 was ever marketed, sold, or distributed at any time during the quarter, please complete all requested fields.
- If the NDC-11 was not marketed, sold, or distributed in a particular quarter, please enter "0" in the total unit volume field and leave the three price fields blank and provide an explanation in the "Explanation of why Manufacturer U.S. Commercial prices were not reported (if applicable)" field of why the NDC-11 had no Manufacturer U.S. commercial prices for that calendar quarter (e.g., the NDC-11 was first marketed in a later quarter).
- Exclude price and volume information for the selected drug for Medicare fee-for-service (Parts A and Part B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care.
- If the Primary Manufacturer and Secondary Manufacturer(s) did not provide financial assistance to patients, please leave the "U.S. commercial average net unit price─ net of patient assistance programs" field blank.

NDC-11	**Quarter**	**Manufacturer U.S. Commercial Average Unit Net Price**	**Manufacturer U.S. Commercial Average Net Unit Price-Net of Patient Assistance Programs**	**Manufacturer U.S. Commercia l Average Net Unit Price-Best**	**NCPDP Unit (EA, ML, GM)**	**Total Unit Volume**	**Total Unit Volume for U.S. Commercial Average Net Unit Price - Best**	**Explanation of why Manufacturer U.S. Commercial prices were not Reported (if applicable)**
12345-6789-01	*QQYYYY*	*$*	*$*	*$*	*Text*	*#*	*#*	*Text (3,600 character count limit, which is approximately 300 words)*

Question 13: Explanation of Information Reported in Response to Question 12: Manufacturer U.S. Commercial Average Net Unit Price

Describe assumptions, methodological steps, and other information for the following topics related to Question 12:

- How sales to enrollees of group and individual commercial plans on- and off-Exchange were determined.
- How discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase

agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to any purchasers were allocated across NDC-11s and calendar quarters.

- If applicable, how financial assistance, such as coupons or co-payment assistance, to patients was allocated across NDC-11s and calendar quarters.
- How information was used to calculate the "U.S. commercial average net unit price," the "U.S. commercial average net unit price— net of patient assistance programs," and the "U.S. commercial average net unit price— best".
- Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

FIELD	RESPONSE FORMAT
Explanation of manufacturer U.S. commercial average net unit price data	*Text (12,000 character count limit, which is approximately 1,000 words)*

Section 6: New Indications and Evidence About Therapeutic Alternatives *(Section I of the Drug Price Negotiation ICR)*

For Questions 14 and 15, the applicable time period to provide the requested responses is from the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original submission of section 1194(e)(2) data to CMS through September 30, 2025.

Question 14. What new information or evidence do you think CMS should be aware of as it evaluates the selected drug and therapeutic alternatives of the selected drug regarding new FDA-approved indication(s) and/or material change in one or more section 1194(e)(2) factor? The submission may include up to 25 citations of new evidence.

FIELD	RESPONSE FORMAT
Free response	*Text* (36,000 character count limit, which is approximately 3,000 words)
Citations	*Up to 25 citations representing new evidence or data* • *Numbered List* • *Citation* • *PubMed ID, if available* • *If the Pub Med ID is not available, the Digital Object Identifier, if available* *Hyperlink, if available*

Question 15. What new information or evidence do you think CMS should be aware of regarding new off-label uses of the selected drug not related to an indicated disease or condition previously considered in negotiation? For off-label use of the selected drug, please indicate and include citations for evidence-based clinical practice guidelines and ensure the off-label use is a medically-accepted indication for drugs covered under Part D or payable under Part B, taking into consideration the major drug compendia, authoritative medical literature, and/or accepted standards of medical practice.

FIELD	RESPONSE FORMAT

Free response	*Text* (36,000 character count limit, which is approximately 3,000 words)
Citations	• *Numbered List* • *Citation* • *PubMed ID, if available* • *If the Pub Med ID is not available, the Digital Object Identifier, if available* • *Hyperlink, if available*
Visual Representations	*Up to 5 attachments representing visual representations of new evidence or data*

Certification of Submission

Required for Any Primary Manufacturer Voluntarily Submitting Responses to this ICR Instruction:

An individual eligible to certify this submission on behalf of the Primary Manufacturer must be one of the following: (1) the chief executive officer (CEO) of the Primary Manufacturer; (2) the chief financial officer (CFO) of the Primary Manufacturer; (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO of the Primary Manufacturer; or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Certification:
I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare reimbursement purposes. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed or is otherwise inaccurate. I also understand that any misrepresentations may also give rise to liability, including under the False Claims Act and/or in the form of civil monetary penalties pursuant to section 1197(c) of the Act.

Check box for certification: [ ]

Contact Information to be entered:

Field	**Response**
Name of the Person Responsible for the Submission	*Text*
Signature	*Text (Electronic Dated Signature or Electronic Copy of Wet Signature Accepted)*

Field	Response
Date	*MMDDYYYY*

Appendix: Email Template for a Primary Manufacturer to Indicate Intent to Submit Voluntary Information for Purposes of Renegotiation of the Selected Drug for Initial Price Applicability Year 2028

Email subject line: Renegotiation: Notice of Intent to Submit Voluntary Information for Initial Price Applicability Year 2028

Body of email:

Dear CMS,

I, an authorized representative of [insert Primary Manufacturer name] for [insert selected drug name], am notifying CMS of my company's intent to submit to CMS voluntary information for the purposes of CMS' consideration of the selected drug for renegotiation-eligibility and selection for initial price applicability year 2028.

Signed, [Insert name of authorized representative]

Paperwork Reduction Act Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1443 (Expires XX/XX/XXXX)**. This is a required information collection to retain or obtain a benefit. Specifically, a Submitting Manufacturer must submit the Selection for Renegotiation-Eligible Drugs Information Collection Request in order to provide information to CMS for use in determining which selected drugs are eligible for renegotiation and will be selected for renegotiation. The time required to complete this information collection is estimated to average 125 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

******CMS Disclosure**** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact Elisabeth Daniel (elisabeth.daniel@cms.hhs.gov).**