Appendix A: Template for Severe Supply Chain Disruption Rebate Reduction Request Form

General Instructions:

To receive consideration for a rebate reduction when there is a severe supply chain disruption, the manufacturer of a Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar must complete Sections 1 through 3, which are:

- Section 1: Identifying Information
- Section 2: Information on the Severe Supply Chain Disruption
- Section 3: Certification

As described in the CY 2025 PFS final rule (89 FR 98584; 98593), CMS has separately defined in its regulations at 42 CFR 427.400 and 428.300 the term "severe supply chain disruption" relative to a Part B rebatable biosimilar biological product or a generic Part D rebatable drug or biosimilar, respectively. In each of these definitions, a severe supply chain disruption means a change in production or distribution that is reasonably likely to lead to a significant reduction in the U.S. supply of a Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar (as applicable) by a manufacturer and significantly affects the ability of the manufacturer to fill orders or meet expected demand for its product in the United States for at least 90 days. These definitions do not include interruptions in manufacturing due to matters such as routine maintenance, manufacturing quality issues, or insignificant changes made in the manufacturing process for the drug.[1]

Submission Method

The manufacturer must email InflationRebateProgram@cms.hhs.gov, with the email subject line "Rebate Reduction Request: Notice of Intent to Submit a Severe Supply Chain Disruption Rebate Reduction Request," indicating the manufacturer's intention to submit a Severe Supply Chain Disruption Rebate Reduction Request for the applicable calendar quarters for Part B or the applicable period for Part D. Within 5 business days of receipt of the email, CMS will provide the manufacturer with the Severe Supply Chain Disruption Rebate Reduction Request form and access to a Box folder, or similar process approved by CMS, specific to the manufacturer's request. CMS continues to evaluate options for manufacturer form submissions and may revise the submission method in the future.

Submissions for a Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar must be made within 60 calendar days of the first day the natural disaster or other unique or unexpected event occurred or began. If a severe supply chain disruption affects multiple Part B rebatable biosimilar biological products or generic Part D rebatable drugs or biosimilars with the same manufacturer, the manufacturer may submit one request for all affected products. If

[1] The term "severe supply chain disruption" is produced above in a single paragraph for ease of discussion. However, 42 CFR 427.400 and 428.300 have similar but distinct definitions for such term as it applies to a Part B rebatable biosimilar biological product or a generic Part D rebatable drug or biosimilar in the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program, respectively.

a manufacturer elects to submit one rebate reduction request for multiple affected products, CMS may grant the reduction request for some products in the request and deny the reduction request for others.

Submission Requirements

The manufacturer is required to complete all sections of the Severe Supply Chain Disruption Rebate Reduction Request form in English and submit the following documentation to the CMS-provided Box folder, or alternative submission method approved by CMS:

- Supporting documentation providing evidence that the severe supply chain disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, a contract manufacturer,[2] or a method of shipping or distribution that the manufacturer uses to make or distribute the Part B rebatable biosimilar biological product(s) or generic Part D rebatable drug(s) or biosimilar(s), such as a change in the production or distribution of the Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar that is reasonably likely to lead to a significant reduction in the U.S. supply of the product by a manufacturer and significantly affects the ability of the manufacturer to fill orders or meet expected demand for its product for at least 90 days.
- Supporting documentation providing evidence that the natural disaster or other unique or unexpected event caused the severe supply chain disruption, including when the natural disaster or other unique or unexpected event occurred or began occurring, and the duration (expected or actual) of the severe supply chain disruption.
- Supporting documentation providing evidence of the manufacturer's physical presence related to manufacturing the rebatable drug in a geographic area where a natural disaster or other unique or unexpected event occurred. If the manufacturer is not physically present in a geographic area where a natural disaster or other unique or unexpected event occurred, but believes there is a severe supply chain disruption caused by a natural disaster or other unique or unexpected event that disrupts the supply chain for a Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar, the manufacturer must submit supporting documentation providing evidence of the impact of the natural disaster or other unique or unexpected event on the supply chain of the Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar. This may include impact on a supplier of an ingredient or packaging material, impact on a contract manufacturer, or impact on the method of shipping or distribution that the manufacturer uses for such products.
- Examples of evidence: records documenting manufacturer ownership of the physical plant where the event occurred, records of insurance claims filed regarding the natural disaster or other unique or unexpected event with relevant dates, dated news reports, dated notification of reduced supply from input distributor or contract manufacturer, and other similar documents.
    - CMS will accept a **maximum of five** news reports, which must include the

[2] A contract manufacturer is a party that performs one or more manufacturing operations on behalf of a manufacturer(s) of active pharmaceutical ingredients (APIs), drug substances, in-process materials, finished drug products, including biological products, and combination products. See "Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry," November 2016: https://www.fda.gov/media/86193/download.

date(s) of publication and a detailed citation for the source of the report (i.e., author of the report and name of the publication [e.g., New York Times]), per Severe Supply Chain Disruption Rebate Reduction Request.

Materials must be submitted in English; any documents not originally in English must be accompanied by an English translation with an attestation that the translation is complete and accurate, as well as the name, address, and a brief statement of the qualifications of the person making the translation.

Certification

The certification of the Severe Supply Chain Disruption Rebate Reduction Request form should be executed by (1) the chief executive officer (CEO) of the generic drug or biosimilar manufacturer, (2) the chief financial officer (CFO) of the generic drug or biosimilar 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 as an authorized representative of the manufacturer to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

If the certification of the Severe Supply Chain Disruption Rebate Reduction Request form is executed by an individual described in (4) above, a letter prepared on official letterhead from the manufacturer must be submitted to CMS to delegate authority to such individual as an authorized representative for purposes of signing the Severe Supply Chain Disruption Rebate Reduction Request form. The letter must include statement of the individual's name, role (e.g., President), the unique identifier(s) assigned by CMS within the Health Plan Management System (HPMS) (i.e., P number(s)), if applicable, and that the purpose of the letter is to designate the individual with the authority to sign Severe Supply Chain Disruption Rebate Reduction Request forms. The letter must be provided on the manufacturer's official letterhead and signed by a senior official of the organization. Manufacturers can designate more than one authorized representative with signatory privileges on a single letter, for example, if the individual signing the Severe Supply Chain Disruption Rebate Reduction Request form will be different from the individual signing the Severe Supply Chain Disruption Rebate Reduction Extension Request form. The letter should be named "Manufacturer Name – Authorized Representative" and uploaded to Box, or transmitted through a similar process approved by CMS, in scanned PDF format.

Section 1: Identifying Information

Identifying information for the manufacturer

Q1. Complete the following table with identifying information for the manufacturer.

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

Q2. Please provide the unique identifier assigned by CMS within the HPMS system (P-number) for the manufacturer for the specific Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar for which this request is being submitted, if applicable.

Unique Identifier Assigned by CMS (P-number): Pnnnn

Identifying information for the rebatable drug

Q3. Complete the following table with identifying information for each NDC-11/HCPCS code of the Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar, as applicable, to which this Severe Supply Chain Disruption Rebate Reduction Request applies:

Field	**Response**
Brand Name	Text
Generic Name or Proper Name	Text
For Part D: NDC-11 For Part B: NDC-11(s) and HCPCS Code	
Specify whether the product to which this Severe Supply Chain Disruption Rebate Reduction Request applies is covered under Medicare Part B, Part D, or both	☐ Part B ☐ Part D ☐ Both

Additional Part B rebatable biosimilar biological products and generic Part D rebatable drugs and biosimilars subject to this Severe Supply Chain Disruption Rebate Reduction Request may be listed in the table in the "Addendum – Additional Products Subject to Request" found at the end of this form.

Section 2: Information on the Severe Supply Chain Disruption

Q4. **Part 1.** If the manufacturer submitted a notification to the Food and Drug Administration (FDA) to report an interruption in manufacturing of any of the Part B rebatable biosimilar biological product(s) or generic Part D rebatable drug(s) or biosimilar(s) as specified under section 506C of the Federal Food, Drug and Cosmetic (FD&C) Act ("506C notification") for which this Severe Supply Chain Disruption Rebate Reduction Request is being submitted, please provide a copy of the 506C notification that was previously submitted to FDA for each Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar. In the box below, please list each such Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar for which a 506C notification was previously submitted to FDA (500 words maximum).

Text

Part 2. If a 506C notification was not submitted to FDA for any of the manufacturer's Part B rebatable biosimilar biological product(s) or generic Part D rebatable drug(s) or biosimilar(s) for which this Severe Supply Chain Disruption Rebate Reduction Request is being submitted, in the box below, please list each such Part B rebatable biosimilar biological product(s) or generic Part D rebatable drug(s) or biosimilar(s) for which a 506C notification has not been submitted to FDA and explain why such notification was not submitted (500 words maximum). Each Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar subject to this Severe Supply Chain Disruption Rebate Reduction Request must be addressed in Part 1 or Part 2 of this question, as applicable.

Text

Q5. Provide an explanation detailing the specifics of the severe supply chain disruption and how the disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, contract manufacturer, or a method of shipping or distribution that the manufacturer uses to make

or distribute the impacted rebatable product(s). Please also provide a description of the natural disaster or other unique or unexpected event the manufacturer believes caused the severe supply chain disruption, including when the natural disaster or other unique or unexpected event occurred or began, the duration (expected or actual) of any change in production or distribution and why that duration is anticipated, as well as when the manufacturer expects supply of the product to meet demand. Include references to any relevant supporting documentation provided and any additional contextual considerations demonstrating the disruption is reasonably likely to lead to a significant reduction in the U.S. supply of the product by a manufacturer and significantly affects the ability of the manufacturer to fill orders or meet expected demand for its product in the United States for at least 90 days (e.g., details surrounding production capacity, existing inventory/stock, transportation routes, or other contextual details). Include specific dates, the FDA Establishment Identifier (FEI) numbers of impacted facilities, and locations, such as an address, as applicable (1000 words maximum):

Text

Q6. Provide a description of actions taken to resolve or mitigate the severe supply chain disruption and why those actions may not be sufficient to alleviate the disruption with references to any relevant supporting documentation provided and any additional contextual considerations (500 words maximum):

Text

Q7. Please indicate any information on this form or in the supporting documentation that the manufacturer believes is proprietary and protected under Exemption 3 and/or 4 of the Freedom of Information Act for CMS consideration. Please reference the specific questions in this form where this information is contained and be specific about the scope of the information believed to be proprietary:

Text

Section 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 inflation rebate purposes, including to determine whether CMS will provide a reduction in the inflation rebate amount for a Part B rebatable biosimilar biological

product or generic Part D rebatable drug or biosimilar that would, absent this request, be subject to the full inflation rebate amount for the specified calendar quarters or applicable period, as described in sections 1847A(i)(3) and 1860D-14B(b)(1) of the Act, respectively. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed. I understand that any misrepresentations may also give rise to liability, including under the False Claims Act.

Yes ☐

No ☐

Contact Information

Field	Response
Name of the Person Responsible for the Submission	Text
Title	Text
Telephone	Text
Email	Text
Signature	× ×
Date	Date

Addendum – Additional Products Subject to Request

Complete the tables below for each additional Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar, as applicable, for which this Severe Supply Chain Disruption Rebate Reduction Request is being submitted.

Field	Response
Brand Name	Text
Generic Name or Proper Name	Text
For Part D: NDC-11 For Part B: NDC-11(s) and HCPCS Code	
Specify whether the product to which this Severe Supply Chain Disruption Rebate Reduction Request applies is covered under Medicare Part B, Part D, or both	☐ Part B ☐ Part D ☐ Both

Field	Response
Brand Name	Text
Generic Name or Proper Name	Text
For Part D: NDC-11 For Part B: NDC-11(s) and HCPCS Code	
Specify whether the product to which this Severe Supply Chain Disruption Rebate Reduction Request applies to a product is covered under Medicare Part B, Part D, or both	☐ Part B ☐ Part D ☐ Both

Field	Response
Brand Name	Text
Generic Name or Proper Name	Text
For Part D: NDC-11 For Part B: NDC-11(s) and HCPCS Code	
Specify whether the product to which this Severe Supply Chain Disruption Rebate Reduction Request applies to a product is covered under Medicare Part B, Part D, or both	☐ Part B ☐ Part D ☐ Both

Field	Response
Brand Name	Text
Generic Name or Proper Name	Text
For Part D: NDC-11 For Part B: NDC-11(s) and HCPCS Code	
Specify whether the product to which this Severe Supply Chain Disruption Rebate Reduction Request applies to a product is covered under Medicare Part B, Part D, or both	☐ Part B ☐ Part D ☐ Both

Field	**Response**
Brand Name	Text
Generic Name or Proper Name	Text
For Part D: NDC-11 For Part B: NDC-11(s) and HCPCS Code	
Specify whether the product to which this Severe Supply Chain Disruption Rebate Reduction Request applies to a product is covered under Medicare Part B, Part D, or both	☐ Part B ☐ Part D ☐ Both

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 OMB **0938-1474 (Expires XX/XX/XXX)**. This information collection includes the forms a manufacturer must submit to be considered for a rebate reduction, as applicable, and the information submitted will be used by CMS to determine whether to grant a reduction in the inflation rebate owed by a manufacturer, if any is owed. The time required to complete this information collection is estimated to average 31 hours per form, including the time to review instructions, search existing data resources, gather the data needed, to review and complete the information collection. This information collection is required to retain or obtain a benefit (sections 1847A(i)(3)(G)(ii), 1860D-14B(b)(1)(C)(ii), and 1860D-14B(b)(1)(C)(iii) of the Social Security Act). Consistent with the confidentiality policy described in 42 CFR 427.402(c)(7), 428.302(c)(7), and 428.303(c)(7), CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. 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).**

Appendix B: Template for Severe Supply Chain Disruption Rebate Reduction Extension Request Form

General Instructions:

To receive consideration for an extension of the reduction of the rebate amount when there is a severe supply chain disruption, the manufacturer of a Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar must complete Sections 1 through 3, which are:

- Section 1: Identifying Information
- Section 2: Information on the Severe Supply Chain Disruption
- Section 3: Certification

As described in the CY 2025 PFS final rule (89 FR 98584; 98593), CMS has separately defined in its regulations at 42 CFR 427.400 and 428.300 the term "severe supply chain disruption" relative to a Part B rebatable biosimilar biological product or a generic Part D rebatable drug or biosimilar, respectively. In each of these definitions, a severe supply chain disruption means a change in production or distribution that is reasonably likely to lead to a significant reduction in the U.S. supply of a Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar (as applicable) by a manufacturer and significantly affects the ability of the manufacturer to fill orders or meet expected demand for its product in the United States for at least 90 days. These definitions do not include interruptions in manufacturing due to matters such as routine maintenance, manufacturing quality issues, or insignificant changes made in the manufacturing process for the drug.[3]

Submission Method

The manufacturer must email InflationRebateProgram@cms.hhs.gov, with the email subject line "Rebate Reduction Request: Notice of Intent to Submit a Severe Supply Chain Disruption Rebate Reduction Extension Request," indicating the manufacturer's intention to submit a Severe Supply Chain Disruption Rebate Reduction Extension Request for the applicable calendar quarters for Part B or the applicable period for Part D. Within 5 business days of receipt of the email, CMS will provide the manufacturer with the fillable Severe Supply Chain Disruption Rebate Reduction Extension Request form and continued access to the Box folder, or similar process approved by CMS, specific to the manufacturer's initial request. CMS continues to evaluate options for manufacturer form submissions and may revise the submission method in the future.

For a natural disaster or other unique or unexpected event that continues into a second applicable period for Part D or fifth calendar quarter for Part B, submissions for a Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar must be made at least 60 calendar days before the start of that second applicable period or fifth calendar quarter, except for

[3] The term "severe supply chain disruption" is produced above in a single paragraph for ease of discussion. However, 42 CFR 427.400 and 428.300 have similar but distinct definitions for such term as it applies to a Part B rebatable biosimilar biological product or a generic Part D rebatable drug or biosimilar in the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program, respectively.

when the initial request for a generic Part D rebatable drug or biosimilar is made less than 60 calendar days before the end of an applicable period such that the initial rebate reduction applied to the next applicable period rather than the applicable period in which the event occurred. In these cases, the rebate reduction extension request must be submitted at least 60 calendar days prior to the end of that next applicable period. If a severe supply chain disruption affects multiple Part B rebatable biosimilar biological products or generic Part D rebatable drugs or biosimilars, the manufacturer may submit one request for all affected products. If a manufacturer elects to submit one rebate reduction extension request for multiple affected products, CMS may grant the reduction request for some products in the request and deny the reduction request for others.

Submission Requirements

The manufacturer is required to complete all sections of the Severe Supply Chain Disruption Rebate Reduction Request Extension form in English and submit any new supporting documentation, if applicable, which includes the following documentation, to the CMS-provided Box folder, or alternative submission method approved by CMS.

- Supporting documentation including new or updated information on why the Part B rebatable biosimilar biological product(s) or generic Part D rebatable drug(s) or biosimilar(s) continues to be affected by the severe supply chain disruption.
- Examples of evidence: notification about reconstruction updates from contractors, dated news reports with updated information on the original event, dated notification of a continued reduction in supply from an input distributor or contract manufacturer,[4] and other similar documents.
    - CMS will accept **a maximum of five** news reports, which must include the date(s) of publication and a detailed citation for the source of the report (i.e., author of the report and name of the publication [e.g., New York Times]), per Severe Supply Chain Disruption Rebate Reduction Extension Request.

Materials must be submitted in English; any documents not originally in English must be accompanied by an English translation with an attestation that the translation is complete and accurate, as well as the name, address, and a brief statement of the qualifications of the person making the translation.

Certification

The certification of the Severe Supply Chain Disruption Rebate Reduction Extension Request form should be executed by (1) the chief executive officer (CEO) of the generic drug or biosimilar manufacturer, (2) the chief financial officer (CFO) of the generic drug or biosimilar 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 as an authorized representative of the manufacturer to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

[4] A contract manufacturer is a party that performs one or more manufacturing operations on behalf of a manufacturer(s) of active pharmaceutical ingredients (APIs), drug substances, in-process materials, finished drug products, including biological products, and combination products. See "Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry," November 2016: https://www.fda.gov/media/86193/download.

If changes need to be made to the manufacturer's authorized representative letter, please provide an updated letter prepared on official letterhead from the manufacturer that designates an authorized representative for purposes of signing the Severe Supply Chain Disruption Rebate Reduction Extension Request form, including: Statement of the individual's name, role (e.g., President), the unique identifier(s) assigned by CMS within the Health Plan Management System (HPMS) (i.e., P number(s)), if applicable, and that the purpose of the letter is to designate the individual with the authority to sign Severe Supply Chain Disruption Rebate Reduction Extension Request forms. The letter must be provided on the manufacturer's official letterhead and signed by a senior official of the organization. Manufacturers can designate more than one authorized representative with signatory privileges on a single letter, for example, if the individual signing the Severe Supply Chain Disruption Rebate Reduction Request form is different from the individual signing the Severe Supply Chain Disruption Rebate Reduction Extension Request form. The letter should be named "Manufacturer Name – Authorized Representative (Version 2)" and be uploaded to Box, or transmitted through a similar process approved by CMS, in scanned PDF format. An email should be sent to InflationRebateProgram@cms.hhs.gov with the subject "Updated Authorized Representative Letter" and the body of the email should indicate that the letter has been uploaded to Box, or transmitted through a similar process approved by CMS.

Section 1: Identifying Information

Identifying information for the manufacturer

Q1. Complete the following table with identifying information for the manufacturer.

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

Q2. Please provide the unique identifier assigned by CMS within the HPMS system (P-number) for the manufacturer for the specific Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar for which this request is being submitted, if applicable.

Unique Identifier Assigned by CMS (P-number): Pnnnn

Identifying information for the rebatable drug

Q3. Complete the following table with identifying information for each NDC-11/HCPCS code of the Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar, as applicable, to which this Severe Supply Chain Disruption Rebate Reduction Extension Request applies.

Field	Response
Brand Name	Text
Generic Name or Proper Name	Text
For Part D: NDC-11 For Part B: NDC-11(s) and HCPCS Code	
Specify whether the product to which this Severe Supply Chain Disruption Rebate Reduction Extension Request applies is covered under Medicare Part B, Part D, or both	☐ Part B ☐ Part D ☐ Both

Additional Part B rebatable biosimilar biological products and generic Part D rebatable drugs and biosimilars subject to this Severe Supply Chain Disruption Rebate Reduction Extension Request may be listed in the table in the "Addendum – Additional Products Subject to Request" found at the end of this form.

Section 2: Information on the Severe Supply Chain Disruption

Q4. **Part 1.** If the manufacturer submitted a notification to the Food and Drug Administration (FDA) to report an interruption in manufacturing of any of the Part B rebatable biosimilar biological product(s) or generic Part D rebatable drug(s) or biosimilar(s) as specified under section 506C of the Federal Food, Drug, and Cosmetic (FD&C) Act ("506C notification") for which this Severe Supply Chain Disruption Rebate Reduction Extension Request is being submitted, please provide a copy of the 506C notification that was previously submitted to FDA, as well as any updates to the initial notification, for each Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar. In the box below, please list each Part B rebatable biosimilar biological product and generic Part D rebatable drug or biosimilar for which a 506C notification, as well as any updates to the initial notification, was previously submitted to FDA (500 words maximum).

Text

Part 2. If a 506C notification was not submitted to FDA for any of the manufacturer's Part B rebatable biosimilar biological product(s) or generic Part D rebatable drug(s) or biosimilar(s) for which this Severe Supply Chain Disruption Rebate Reduction Extension Request is being submitted, in the box below, please list each such Part B rebatable biosimilar biological product(s) or generic Part D rebatable drug(s) or biosimilar(s) for which a 506C notification has not been submitted to FDA and why such notification was not submitted (500 words maximum). Each Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar subject to this Severe Supply Chain Disruption Rebate Reduction Extension Request must be addressed in Part 1 or Part 2 of this question, as applicable.

Text

Q5. Provide a detailed explanation of actions the manufacturer has taken to resolve or mitigate the severe supply chain disruption and why efforts have not been adequate to resolve the severe supply chain disruption. If this Severe Supply Chain Disruption Rebate Reduction Extension Request does not apply to all products for which a Severe Supply Chain Disruption Rebate Reduction Request was granted, please explain how the severe supply chain disruption was resolved for those products. Include references to any relevant supporting documentation provided and any additional contextual considerations (750 words maximum):

Text

Q6. Provide an explanation detailing any new information on the specifics of the severe supply chain disruption that was not previously submitted and how the disruption continues to impact the manufacturer itself, a supplier of an ingredient or packaging, contract manufacturer, or a method of shipping or distribution that the manufacturer uses to make or distribute the impacted rebatable product(s). Please also provide an explanation detailing any new information that was not previously submitted about the natural disaster or other unique or unexpected event the manufacturer believes caused the severe supply chain disruption, including updated information on the duration (expected or actual) of any change in production or distribution, why that duration is anticipated, and when the manufacturer expects supply of the product to meet demand. Include specific dates, the FDA Establishment Identifier (FEI) numbers of impacted facilities, and locations, such as an address, as applicable. Include references to any relevant supporting documentation provided and any additional contextual considerations (750 words maximum):

Text

Q7. Please indicate any information on this form or in the supporting documentation that the manufacturer believes is proprietary and protected under Exemption 3 and/or 4 of the Freedom of Information Act for CMS consideration. Please reference the specific questions in this form where this information is contained and be specific about the scope of the information believed to be proprietary:

Text

Section 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 inflation rebate purposes, including to determine whether CMS will provide a reduction in the inflation rebate amount for a Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar that would, absent this request, be subject to the full inflation rebate amount for the specified calendar quarters or applicable period, as described in sections 1847A(i)(3) and 1860D-14B(b)(1) of the Act, respectively. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed. I understand that any misrepresentations may also give rise to liability, including under the False Claims Act.

Yes ☐
No ☐

Contact Information

Field	Response
Name of the Person Responsible for the Submission	Text
Title	Text
Telephone	Text
Email	Text
Signature	× ×
Date	Date

Addendum – Additional Products Subject to Request

Complete the tables below for each additional Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar for which this Severe Supply Chain Disruption Rebate Reduction Extension Request is being submitted.

Field	Response
Brand Name	Text
Generic Name or Proper Name	Text
For Part D: NDC-11 For Part B: NDC-11(s) and HCPCS Code	
Specify whether the product to which this Severe Supply Chain Disruption Rebate Reduction Extension Request applies is covered under Medicare Part B, Part D, or both	☐ Part B ☐ Part D ☐ Both

Field	Response
Brand Name	Text
Generic Name or Proper Name	Text
For Part D: NDC-11 For Part B: NDC-11(s) and HCPCS Code	
Specify whether the product to which this Severe Supply Chain Disruption Rebate Reduction Extension Request applies is covered under Medicare Part B, Part D, or both	☐ Part B ☐ Part D ☐ Both

Field	Response
Brand Name	Text
Generic Name or Proper Name	Text
For Part D: NDC-11 For Part B: NDC-11(s) and HCPCS Code	
Specify whether the product to which this Severe Supply Chain Disruption Rebate Reduction Extension Request applies is covered under Medicare Part B, Part D, or both	☐ Part B ☐ Part D ☐ Both

Field	Response
Brand Name	Text
Generic Name or Proper Name	Text
For Part D: NDC-11 For Part B: NDC-11(s) and HCPCS Code	
Specify whether the product to which this Severe Supply Chain Disruption Rebate Reduction Extension Request applies is covered under Medicare Part B, Part D, or both	☐ Part B ☐ Part D ☐ Both

Field	**Response**
Brand Name	Text
Generic Name or Proper Name	Text
For Part D: NDC-11 For Part B: NDC-11(s) and HCPCS Code	
Specify whether the product to which this Severe Supply Chain Disruption Rebate Reduction Extension Request applies is covered under Medicare Part B, Part D, or both	☐ Part B ☐ Part D ☐ Both

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 OMB **0938-1474 (Expires XX/XX/XXXX)**. This information collection includes the forms a manufacturer must submit to be considered for a rebate reduction, as applicable, and the information submitted will be used by CMS to determine whether to grant a reduction in the inflation rebate owed by a manufacturer, if any is owed. The time required to complete this information collection is estimated to average 31 hours per form, including the time to review instructions, search existing data resources, gather the data needed, to review and complete the information collection. This information collection is required to retain or obtain a benefit (sections 1847A(i)(3)(G)(ii), 1860D-14B(b)(1)(C)(ii), and 1860D-14B(b)(1)(C)(iii) of the Social Security Act). Consistent with the confidentiality policy described in 42 CFR 427.402(c)(7), 428.302(c)(7), and 428.303(c)(7), CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. 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).**