Appendix C: Template for Likely to be in Shortage Rebate Reduction Request Form

General Instructions:

To receive consideration for a rebate reduction when a generic Part D rebatable drug is likely to be in shortage, the manufacturer must complete Sections 1 through 3, which are:

- Section 1: Identifying Information
- Section 2: Information on Likely Shortage
- Section 3: Certification

A generic Part D rebatable drug is considered likely to be in shortage if CMS determines that without such reduction or waiver, the generic Part D rebatable drug is likely to be described as in shortage on the shortage list authorized under section 506E of the Federal Food, Drug and Cosmetic (FD&C) Act during a subsequent applicable period. Biosimilars are not eligible for Likely to be in Shortage Rebate Reductions. Section 1860D-14B(b)(1)(C)(iii) of the Social Security Act ("the Act") does not provide examples of reasons that a generic Part D rebatable drug may be likely to be in shortage in a subsequent applicable period, and CMS believes that many causes of likely shortage would be covered under the severe supply chain disruption reduction policy described in 42 CFR 428.302. Thus, CMS expects Likely to be in Shortage Rebate Reductions to apply to generic Part D rebatable drugs that are likely to be in shortage for reasons that are distinct from those under the severe supply chain disruption policy. CMS anticipates that a generic Part D rebatable drug may qualify for a Likely to be in Shortage Rebate Reduction if the manufacturer of a generic Part D rebatable drug experiences a significant increase in the demand of the drug because, for example, other manufacturers of the drug recently discontinued production of the drug, leaving the manufacturer of the generic Part D rebatable drug as the sole manufacturer and likely unable to meet demand or because of an expansion of the approved or accepted indications of the drug in nationally recognized, evidence-based guidelines and CMS-approved Part D compendia.

Submission Method

The manufacturer must email InflationRebateProgram@cms.hhs.gov, with the email subject line "Rebate Reduction Request: Notice of Intent to Submit a Likely to be in Shortage Rebate Reduction Request," indicating the manufacturer's intention to submit a Likely to be in Shortage Rebate Reduction Request for a generic Part D rebatable drug for the applicable period within the specified timeframe noted below. Within 5 business days of receipt of the email, CMS will provide the manufacturer with the Likely to be in Shortage 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.

An authorized representative of the manufacturer (as defined below) must submit to CMS a complete Likely to be in Shortage Rebate Reduction Request form, along with all supporting documentation, at least 60 calendar days before the start of the next applicable period in which the generic Part D rebatable drug is likely to be in shortage to qualify for the reduction during the applicable period in which the request is submitted. For complete requests submitted with less

than 60 calendar days remaining in the applicable period, CMS will apply any reduction of the rebate amount during the next applicable period in which the generic Part D rebatable drug is likely to be in shortage. To receive consideration for a rebate reduction under this provision, the request must be submitted to CMS before the start of the next applicable period in which the generic Part D rebatable drug is likely to be in shortage. If multiple generic Part D rebatable drugs are likely to be in shortage in a subsequent applicable period, the manufacturer may submit one request for all affected products. If 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 Likely to be in Shortage 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 of the circumstances leading the manufacturer to describe the drug as likely to be in shortage.
- Examples of evidence: reports that other manufacturers recently discontinued production of a generic Part D rebatable drug such that the remaining manufacturer has experienced a significant increase in demand of the drug, or documentation of order requests with volume well in excess of shipped units, or documentation or communication with suppliers or contract manufacturers[1] showing issues acquiring active pharmaceutical ingredients (API) or raw materials necessary to manufacture the drug or similar supply chain issues that could foreseeably limit the supply or manufacturing of the drug.
    - 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 Likely to be in Shortage 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.

[1] 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.

Certification

The certification of the Likely to be in Shortage Rebate Reduction Request form should be executed by (1) the chief executive officer (CEO) of the generic drug manufacturer, (2) the chief financial officer (CFO) of the generic drug 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 Likely to be in Shortage Rebate Reduction Request form is executed by an individual described in (4) above, the manufacturer must submit to CMS a letter prepared on official letterhead to delegate authority to such individual as an authorized representative for purposes of signing the Likely to be in Shortage 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 Likely to be in Shortage 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 Likely to be in Shortage Rebate Reduction Request form will be different from the individual signing the Likely to be in Shortage 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 generic Part D rebatable drug 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 of the generic Part D rebatable drug to which this Likely to be in Shortage Rebate Reduction Request applies:

Field	Response
Generic Name	Text
NDC-11	

Additional generic Part D rebatable drugs subject to this Likely to be in Shortage 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 Likely Shortage

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 generic Part D rebatable drug(s) as specified under section 506C of the FD&C Act ("506C notification") for which this Likely to be in Shortage Rebate Reduction Request is being submitted, please provide a copy of the 506C notification(s) that was previously submitted to FDA for each generic Part D rebatable drug. In the box below, please list each such generic Part D rebatable drug 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 generic Part D rebatable drug(s) for which this Likely to be in Shortage Rebate Reduction Request is being submitted, in the box below, please list each such generic Part D rebatable drug(s) for which a 506C notification has not been submitted to FDA and explain why such notification was not submitted (500 words maximum). Each generic Part D rebatable drug subject to this Likely to be in Shortage Rebate Reduction Request

must be addressed in Part 1 or Part 2 of this question, as applicable.

Text

Q5. Provide an explanation of the potential shortage, including the anticipated cause(s) of the shortage and why the manufacturer believes the generic Part D rebatable drug is likely to be described as in shortage on the shortage list in a subsequent applicable period. Include references to any relevant supporting documentation provided and any additional contextual considerations demonstrating that the generic Part D rebatable drug is likely to be in shortage (750 words maximum):

Text

Q6. Provide the anticipated start date and duration of the potential shortage, and an explanation of the actions the manufacturer is taking to avoid the potential shortage, why those actions may not be sufficient, and how the reduction of the rebate amount would reduce the likelihood of the drug being listed on the FDA shortage list. 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 generic Part D rebatable drug that would, absent this request, be subject to the full inflation rebate amount for the specified applicable period, as described in Section 1860D-14B(b)(3) of the 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. 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	X [redacted] X [redacted]
Date	Date

Addendum – Additional Products Subject to Request

Complete the table below for each additional generic Part D rebatable drug for which this Likely to be in Shortage Rebate Reduction Request is being submitted.

Field	**Response**
Generic Name	Text
NDC-11	

Field	Response
Generic Name	Text
NDC-11	

Field	Response
Generic Name	Text
NDC-11	

Field	Response
Generic Name	Text
NDC-11	

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).**

Appendix D: Template for Likely to be in Shortage Rebate Reduction Extension Request Form

General Instructions:

To receive consideration for an extension of the reduction of the rebate amount when there is a likely shortage, the manufacturer of a generic Part D rebatable drug must complete Sections 1 through 3, which are:

- Section 1: Identifying Information
- Section 2: Information on Likely Shortage
- Section 3: Certification

A generic Part D rebatable drug is considered likely to be in shortage if CMS determines that without such reduction or waiver, the generic Part D rebatable drug is likely to be described as in shortage on the shortage list authorized under section 506E of the Federal Food, Drug and Cosmetic (FD&C) Act during a subsequent applicable period. Biosimilars are not eligible for Likely to be in Shortage Rebate Reductions. Section 1860D-14B(b)(1)(C)(iii) of the Social Security Act ("the Act") does not provide examples of reasons that a generic Part D rebatable drug may be likely to be in shortage in a subsequent applicable period, and CMS believes that many causes of likely shortage would be covered under the severe supply chain disruption reduction policy described in 42 CFR 428.302. Thus, CMS expects Likely to be in Shortage Rebate Reductions to apply to generic Part D rebatable drugs that are likely to be in shortage for reasons that are distinct from those under the severe supply chain disruption policy. CMS anticipates that a generic Part D rebatable drug may qualify for a Likely to be in Shortage Rebate Reduction if the manufacturer of a generic Part D rebatable drug experiences a significant increase in the demand of the drug because, for example, other manufacturers of the drug recently discontinued production of the drug, leaving the manufacturer of the generic Part D rebatable drug as the sole manufacturer and likely unable to meet demand or because of an expansion of the approved or accepted indications of the drug in nationally recognized, evidence-based guidelines and CMS-approved Part D compendia.

Submission Method

The manufacturer must email InflationRebateProgram@cms.hhs.gov, with the email subject line "Rebate Reduction Request: Notice of Intent to Submit a Likely to be in Shortage Rebate Reduction Extension Request," indicating the manufacturer's intention to submit a Likely to be in Shortage Rebate Reduction Extension Request for a generic Part D rebatable drug for the second applicable period within the specified timeframe noted below. Within 5 business days of receipt of the email, CMS will provide the manufacturer with the Likely to be in Shortage 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.

An authorized representative of the manufacturer (as defined below) must submit to CMS a complete Likely to be in Shortage Rebate Reduction Extension Request form, along with all supporting documentation, at least 60 calendar days before the start of the second applicable

period in which the generic Part D rebatable drug is likely to be in shortage. 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 for some products in the request and deny the reduction for others.

Submission Requirements

The manufacturer is required to complete all sections of the Likely to be in Shortage Rebate Reduction Extension Request form in English and submit any new supporting documentation, if applicable, which includes new or updated information on why the generic Part D rebatable drug is likely to be in shortage during the second applicable period, to the CMS-provided Box folder, or alternative submission method approved by CMS.

- Examples of evidence: reports that the manufacturer continues to experience a significant increase in demand of the drug, or documentation or communication with suppliers or contract manufacturers[2] showing continued issues acquiring active pharmaceutical ingredients (API) or raw materials necessary to manufacture the drug or similar supply chain issues that could foreseeably limit the supply or manufacturing of the drug.
    - 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 Likely to be in Shortage 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 Likely to be in Shortage Rebate Reduction Extension Request form should be executed by (1) the chief executive officer (CEO) of the generic drug manufacturer, (2) the chief financial officer (CFO) of the generic drug 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 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 Likely to be in Shortage Rebate Reduction Extension Request form, including: Statement of the individual's name, role (e.g., President), 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.

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 Likely to be in Shortage 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 Likely to be in Shortage Rebate Reduction Request form is different from the individual signing the Likely to be in Shortage 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 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 generic Part D rebatable drug 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 of the generic Part D rebatable drug to which this Likely to be in Shortage Rebate Reduction Extension Request applies:

Field	Response
Generic Name	Text
NDC-11	

Additional generic Part D rebatable drugs subject to this Likely to be in Shortage 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 Likely Shortage

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 generic Part D rebatable drug(s) as specified under section 506C of the FD&C Act ("506C notification") for which this Likely to be in Shortage 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 original notification, for each generic Part D rebatable drug. In the box below, please list each generic Part D rebatable drug 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 generic Part D rebatable drug(s) for which this Likely to be in Shortage Rebate Reduction Extension Request is being submitted, in the box below, please list each such generic Part D rebatable drug(s) for which a 506C notification has not been submitted to FDA and explain why such notification was not submitted (500 words maximum). Each generic Part D rebatable drug subject to this Likely to be in Shortage 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 likelihood of the generic Part D rebatable drug(s) to be in shortage and why efforts have not been adequate to resolve the potential concern(s). If this Likely to be in Shortage Rebate Reduction Extension Request does not apply to all products for which a Likely to be in Shortage Rebate Reduction Request was granted, please explain how the likely shortage 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 potential shortage that was not previously submitted, including details on whether the original anticipated cause(s) of the shortage occurred and why the manufacturer believes the generic Part D rebatable drug is likely to be described as in shortage on the shortage list in a second applicable period. Include references to any relevant supporting documentation provided and any additional contextual considerations (750 words maximum):

Text

Q7. Provide updated information on the estimated start date and duration of the potential shortage and how the continued reduction of the rebate amount would reduce the likelihood of the drug ending up on the FDA shortage list. Include references to any relevant supporting documentation provided and any additional contextual considerations (750 words maximum):

Text

Q8. 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 generic Part D rebatable drug that would, absent this request, be subject to the full inflation rebate amount for the specified applicable period, as described in Section 1860D-14B(b)(3) of the 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. 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 generic Part D rebatable drug for which this Likely to be in Shortage Rebate Reduction Extension Request is being submitted.

Field	**Response**
Generic Name	Text
NDC-11	

Field	**Response**
Generic Name	Text
NDC-11	

Field	**Response**
Generic Name	Text
NDC-11	

Field	Response
Generic Name	Text
NDC-11	

Field	Response
Generic Name	Text
NDC-11	

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).**