Small Biotech Exception and Biosimilar Delay 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 for Initial Price Applicability Year 2027 includes two parts: Part 1 (Small Biotech Exception Information Collection Request Form) and Part 2 (Biosimilar Delay Information Collection Request Form).

For the purposes of this information collection request (ICR), all defined terms referenced in this ICR have their meaning set forth in the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (expected to be issued in Spring 2024 concurrently with this ICR; referenced hereinafter as the "Medicare Drug Price Negotiation Program Draft Guidance").

PART 1

Small Biotech Exception Information Collection Request 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 accurately identify, at the request of a manufacturer ("Submitting Manufacturer"), whether a given qualifying single source drug qualifies for the SBE for initial price applicability year 2027 in accordance with section 1192(d)(2) of the Act, CMS needs to collect information to identify the entity that had a Medicare Coverage Gap Discount Program (CGDP) Agreement under section 1860D-14A[1] for the drug in effect on December 31, 2021, including all other entities that, as of December 31, 2021, were treated as a single employer with that entity under subsection (a) or (b) of section 52 of the Internal Revenue Code (IRC) of 1986 and had a Medicare CGDP Agreement in effect on December 31, 2021. Accordingly, for the purpose of the SBE, "controlled group" of the manufacturer means all corporations or partnerships, sole proprietorships, and other entities that were treated as a single employer under section 52(a) or (b) of the IRC and the Department of the Treasury regulations thereunder with the 2021 Manufacturer.

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 of such drug is acquired after 2021 by

[1] OMB control number: 0938-0982.

another entity that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(C)(ii)[2]. Because the earliest effective date for this limitation is January 1, 2025 for acquisitions prior to January 1, 2025, this requirement applies to requests for the SBE starting in initial price applicability year 2027.

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. This ICR only collects information relevant to a manufacturer's request for the SBE for initial price applicability year 2027. 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.

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.
- As described in section 30.2.1 of the Medicare Drug Price Negotiation Program 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)(s) for the qualifying single source drug may be the Submitting Manufacturer.
- If the Submitting Manufacturer 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 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 Health Plan Management

[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.

System (HPMS)" PDF. Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.[3] Technical assistance will also be made available.

- Requests for an SBE that are incomplete or not timely submitted via the CMS HPMS will not be accepted. This form must be completed and submitted within the CMS HPMS by the date specified by CMS in program instruction.
- 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, the unique identifier(s) assigned by CMS to the Submitting Manufacturer (P number(s)[4]), and all labeler codes;
    - Disclosure of whether the Submitting Manufacturer 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);
        - 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
    - Identifying information as of December 31, 2021 for the entity that had a Medicare CGDP Agreement for the qualifying single source drug in effect on December 31, 2021, and all members of that entity's controlled group that had a Medicare CGDP Agreement in effect on December 31, 2021.
- All submissions require certification. The certification of the ICR should be executed by (1) the 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).

Questions:

Question 1: Please provide the following information about the Submitting Manufacturer as of the date of submission of this form:

Field	**Response**
Entity Name	Text

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

[4] 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.

Field	Response
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Mailing Address	Text
Unique Identifier Assigned by CMS (P number)[5]	Pnnnn
Labeler Code(s)	Nnnnn

Question 2a: Was the Submitting Manufacturer 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.

Question 2b: If you answered "Yes" to Question 2a above, please provide the following information about the acquiring entity.

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

Question 3a: Please list the active moiety (for drug products) or active ingredient (for biological products) for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception.

Active moiety / active ingredient
Text

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

[5] 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.

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 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?

Yes/No

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

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)	Nnnnn

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: 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)	nnnnn

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

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, 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. I also 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
Signature	Text
Date	Date

PART 2

Biosimilar Delay Information Collection 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; therefore, no Reference Drugs would be the subject of an Additional Delay Request in initial price applicability year 2027.

In accordance with section 30.1 of the Medicare Drug Price Negotiation Program Draft Guidance, in order for CMS to determine if the requirements in section 1192(f) for an Initial Delay Request are met, the Biosimilar Manufacturer must submit identifying information and make attestations:

1. Identifying information for the Biosimilar Manufacturer, the Biosimilar, the Biosimilar's reference product, and the Reference Manufacturer;
2. Attestation that the Biosimilar Manufacturer must not be the same as the Reference Manufacturer and must 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 not have entered into an agreement that either:
    i. requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request; or
    ii. 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, 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, 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.

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 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). The process for submitting an Initial Delay Request for initial price applicability year 2028 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 via the CMS HPMS.[6] Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS)" PDF. Instructions for gaining signatory access to HPMS are also included in this PDF.[7] Technical assistance will also be made available.
- As described in section 30.3.1 of the Medicare Drug Price Negotiation Program 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

[6] 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.

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

been licensed, the sponsor of the BLA for the Biosimilar that has been submitted for review by 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, the Biosimilar Manufacturer must submit a complete Initial Delay Request to CMS via the CMS HPMS no later than mid-December (to be specified in a later version of this ICR). 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.
- 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.

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[8])	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 for licensure for the Biosimilar under section 351(k) of the Public Health Service Act regardless of status (i.e., including applications that are approved, accepted for review, and submitted but not yet accepted for review). Select the current status and relevant date.

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

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).

Field	Response
Reference Product	Text
Reference Manufacturer	Text

[8] 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.

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) 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 if CMS determines there is a high likelihood that the Biosimilar will be licensed and marketed before February 1, 2027. 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 if CMS determines there is a high likelihood that the Biosimilar will be licensed before February 1, 2027. 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. PT on January 15, 2025, 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 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.	☐

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 if CMS determines there is a high likelihood that the Biosimilar will be marketed before February 1, 2027.

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

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

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, 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. I also 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
Signature	Text
Date	Date

PRA Disclosure Statement