Small Biotech Exception Information Collection Request (ICR) Form (CMS-10844, OMB 0938-NEW)

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(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")[1].

In order to accurately identify, at the request of a manufacturer, whether a given qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026 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 Agreement under section 1860D-14A[2] for the drug as of 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 of 1986 and 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, proprietorships, and other entities treated as a single employer under 26 U.S. Code section 52(a) or (b).

Note: This information collection request does not collect all information that may be relevant to a manufacturer's request for the Small Biotech Exception for initial price applicability years other than 2026. For example, this information collection request does not collect all information relevant to the statutory limitation found in section 1192(d)(2)(B)(ii) of the Act (which precludes the application of the Small Biotech Exception to a qualifying single source drug if the manufacturer of that drug is acquired after 2021 by a manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii)) because the earliest effective date specified in that limitation (January 1, 2025) has no impact until initial price applicability year 2027 (the first initial price applicability year with a selected drug publication date after January 1, 2025). Additionally, this information collection request does not collect all information relevant to Part B drugs, as Part B drugs may not be selected for negotiation until initial price applicability year 2028, in accordance with section 1192(a)(3) of the Act.

A determination by CMS that a given qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026 does not mean that this drug will continue to qualify for the Small Biotech Exception for future initial price applicability years.

[1] For the purposes of this information collection request, qualifying single source drug has the same definition as it is given in section 30.1 of the Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments ("Initial Negotiation Program Guidance" – see https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf).

[2] OMB control number: 0938-0982

The process for submitting a request for a drug to qualify for the Small Biotech Exception for initial price applicability years 2027 and 2028 will be addressed in future guidance.

Instructions for Completing the Small Biotech Exception Information Collection Request Form:

A manufacturer that seeks the Small Biotech Exception for its qualifying single source drug ("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 2026. 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 Medicare Coverage Gap Discount Program agreement for the drug on December 31, 2021. As described in section 30.2.1 of the Initial Negotiation Program 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) or Biologics License Application(s) for the qualifying single source drug may be the Submitting Manufacturer.

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)), and all labeler codes;
- Identifying information about the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception:
    - Active moiety (for drug products) or active ingredient (for biological products);
    - All New Drug Applications (NDAs) held by the Submitting Manufacturer for any drug products with the active moiety or all Biologics License Applications (BLAs) held by the Submitting Manufacturer for any biological products with the active ingredient; and
    - All 11-digit National Drug Codes (NDCs) for drug or biological products with the active moiety or active ingredient, as applicable, and marketed pursuant to any of the NDAs or BLAs identified in the previous sub-bullet, that were (A) sold or marketed during 2021 or (B) end-dated prior to December 31, 2021;
- Identifying information as of December 31, 2021 for the entity that had a Medicare Coverage Gap Discount Program agreement for the qualifying single source drug on December 31, 2021, and all members of that entity's controlled group that had a Medicare Coverage Gap Discount Program agreement in effect on December 31, 2021; and
- A certification by (1) the chief executive officer (CEO), (2) the chief financial officer (CFO), (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Additional instructions for submitting this form are as follows:

- This form must be completed and submitted within the CMS Health Plan Management System (HPMS) by the date specified by CMS in program instruction.
- A separate form must be submitted for each qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception.

Department of Health and Human Services

Centers for Medicare & Medicaid Services

Small Biotech Exception Information Collection Request 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(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").

In order to accurately identify, at the request of a manufacturer, whether a given qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026 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 Agreement under section 1860D-14A[i] for the drug as of 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 of 1986 and 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, proprietorships, and other entities treated as a single employer under 26 U.S. Code section 52(a) or (b).

A manufacturer that seeks the Small Biotech Exception for its qualifying single source drug ("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 2026.

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

Field	**Response**
Entity Name	
Employer Identification Number(s)	
Mailing Address	
Unique Identifier Assigned by CMS (P-number)[ii]	
Labeler Code(s)	

Question 2a: 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

Question 2b: Please list all New Drug Applications (NDAs) held by the Submitting Manufacturer for any drug products with the active moiety listed in Question 2a, or all Biologics License Applications (BLAs) held by the Submitting Manufacturer for any biological products with the active ingredient listed in Question 2a, as applicable.

Application Number (123456)	Application Type (NDA; BLA)	Submission Number (123)	Approval Date (MM/DD/YYYY)	NDA/BLA holder

Add a separate row for each additional NDA / BLA.

Question 3: Please list all 11-digit National Drug Codes (NDCs) for drug or biological products with the active moiety or active ingredient identified in Question 2a, as applicable, and marketed pursuant to any of the NDAs or BLAs identified in Question 2b, that were (A) sold or marketed during 2021 or (B) end-dated prior to December 31, 2021 for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception.

NDC-11 Number(s) (format 12345-6789-01)

Add a separate row for each additional NDC-11.

Question 4a: On December 31, 2021, did the Submitting Manufacturer have a Coverage Gap Discount Program agreement 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 5.

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

Field	Response
Entity Name	
Employer Identification Number(s) (EIN(s))	
Address	
Unique Identifier Assigned by CMS (P-number)	
Labeler Code(s)	

Question 5a: Did the entity that had a Coverage Gap Discount Program agreement effective 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, proprietorships and other entities treated as a single employer under 26 U.S. Code section 52(a) or (b).

Yes []

No [].

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 effective on December 31, 2021, for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception. Only include members of the controlled group that had a Medicare Coverage Gap Discount Program agreement in effect on December 31, 2021.

Field	Response
Entity Name	
Employer Identification Number(s) (EIN(s))	
Address	
Unique Identifier Assigned by CMS (P-number)	
Labeler Code(s)	

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 []

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-XXXX (Expires XX/XX/XXXX)**. This is a required information collection to retain or obtain a benefit. Specifically, a manufacturer must submit the Small Biotech Exception Information Collection Request in order for its qualifying single source drug to be considered for the Small Biotech Exception. The time required to complete this information collection is estimated to average 6.5 hours per response for drugs not acquired after December 31, 2021, and 12.25 hours for drugs acquired after December 31, 2021, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

[i] OMB 0938-0982

[ii] The unique identifier (P-Number) means the identifier assigned by CMS when the manufacturer enters into an agreement under section 1860D-14A.