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March 27, 2023

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Agency Information Collection Activities: Proposed Collection; Comment Request [CMS-10844]

Dear Mr. Parham:

Incyte appreciates the opportunity to submit comments in response to the Centers for Medicare and Medicaid Services' (CMS's) Information Collection Request (ICR) regarding the Small Biotech Exception from the Medicare Drug Price Negotiation Program (Program).[1] Incyte is a U.S.-based biopharmaceutical company founded on the premise that investment in strong science and the relentless pursuit of research and development (R&D) excellence can translate into new solutions that can positively affect patients' lives.

Incyte recognizes that CMS has a significant task ahead to implement the provisions of the Inflation Reduction Act (IRA). We appreciate that this ICR to identify small biotech drugs is one of the Agency's first public actions. Incyte intends to submit information on Jakafi® in order to qualify for the Small Biotech Exception.

Incyte's R&D team in Wilmington, Delaware discovered and developed Jakafi® (ruxolitinib) ("Jakafi"). Jakafi is an oral tablet drug that is FDA-approved in 5mg, 10mg, 15mg, 20mg, and 25mg dosage strengths for the treatment of: (1) "intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults"; (2) "polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea"; (3) "steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older"; and (4) "chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older." *See* Jakafi Prescribing Information.[2] With respect to the first three of these indications, Jakafi was the first FDA-approved branded pharmaceutical treatment for patients having these serious diseases.

In 2022 alone, Incyte invested $1.6 billion on R&D, representing nearly 47% of the company's total net revenues during that time. Revenue from sales of our approved products, chiefly Jakafi, fuel Incyte's clinical development program of 25 investigational medicines intended to transform the treatment of cancer and inflammatory and

[1] 88 Fed. Reg. 4184 (Jan. 24, 2023).
[2] https://www.jakafi.com/pdf/prescribing-information.pdf

autoimmune conditions.[3]

Incyte's marketed products now include Opzelura™ (ruxolitinib) cream and Pemazyre® (pemigatinib), which also were discovered and developed in-house at Incyte's R&D headquarters in Delaware and represent first-in-class treatments for patients suffering from nonsegmental vitiligo, cholangiocarcinoma, and myeloid/lymphoid neoplasms (MLNs). We are purposeful in focusing our science in areas where we believe we can have a significant impact, regardless of the disease or size of the patient population. We are proud that this approach has resulted in a strong heritage of Incyte-discovered, first-in-class medicines for patients.

Jakafi meets the statutory definitions for the Small Biotech Exception as outlined in the IRA. Incyte's comments to CMS include the following recommendations:

I. Publish a List of Part D Drugs that Qualify for the Small Biotech Exception in 2026
II. Provide Flexibility for Manufacturers When Submitting the Small Biotech Exception Information Collection Request Form
III. Clarify the "New Formulations" Provision of the Small Biotech Exception
IV. Clarify Data Elements Included on the Small Biotech Form
    a. Define if Manufacturers Need to Submit NDC-11s Only for the Small Biotech Drug, or If the Submission Should Include NDC-11s for All "Qualified Single Source Drugs", as Determined By CMS (Question 2)
    b. Specify that Manufacturers Should Submit Controlled Group Information Only for Those Entities Which Had a Coverage Gap Discount Program Agreement with CMS (Question 4)
    c. Limit the Scope of the Certification to the Drug Price Negotiation Program

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I. CMS Should Publish a List of Part D Drugs that Qualify for the Small Biotech Exception in 2026

The ICR proposes to collect information from manufacturers to determine if any of the manufacturer's products meets the Small Biotech Exception with respect to initial price applicability year 2026.[4] After manufacturers request this exemption, Incyte encourages CMS to publish a complete list of Part D drugs that qualify for the Small Biotech Exception for price applicability period 2026. A published list will provide Incyte and other qualifying manufacturers with much-needed certainty about whether their products qualify for the Small Biotech Exception and will give Incyte the confidence to continue reinvesting nearly 50% of our revenue in R&D, which we believe is consistent with Congressional intent.

Congress' intention for the small biotech provisions of the IRA were referenced in the principles released by the Senate Finance Committee Chair Ron Wyden (D-OR) in June 2021.[5] The document recognizes that "groundbreaking new treatments" targeted at unmet need "can largely be traced back to small biotechnology companies that take on a disproportionate share of the risk of R&D" and references the committee's intent to "protect [small biotechnology companies'] ability to innovate."[6] Publishing the list of qualifying exempted drugs is

[3] Incyte Corporation Pharmaceutical Portfolio, https://www.incyte.com/what-we-do/pharmaceutical-portfolio (last visited March 6, 2023).
[4] Small Biotech ICR Form (CMS 10844, OMB 0938-NEW) at 1.
[5] Senate Finance Committee (2021, June 22). *Principles for Drug Pricing Reform*. finance.senate.gov. Retrieved March 3, 2023, from https://www.finance.senate.gov/imo/media/doc/062221%20SFC%20Drug%20Pricing%20Principles.pdf
[6] *Id.*

consistent with congressional intent because it will provide Incyte and similar companies with the continued confidence to invest in the next generation of treatments.

Incyte believes that publication of the Small Biotech Exceptions list creates minimal additional burden for CMS since the Agency will already have collected and analyzed the data to establish this list internally prior to publishing the selected drug list,[7] and it would be an appropriate complement to HHS's publication of the Part D drugs selected for Medicare negotiation in 2026. As further evidence of the minimal burden, the Agency estimates that the number of Part D drugs that qualify for the small biotech exception in 2026 to be 10, the same number of drugs that the agency will publicize as part of its statutorily-set selection of 10 Part D drugs for negotiation.[8]

Subsequent to the publication of the ICR, CMS issued a separate guidance on the Medicare Drug Price Negotiation Program that includes additional considerations for Small Biotech Drugs.[9] In the March 15 guidance, CMS states that "The Submitting Manufacturer must resubmit a request for the drug to be considered for the exception for the initial price applicability years 2027 and 2028." As such, Incyte encourages the Agency to publish updated lists of excepted drugs in subsequent years.

II. CMS Should Provide Flexibility for Manufacturers When Submitting the Small Biotech Exception Information Collection Request Form

CMS states its intent to "develop an automated tool within an existing information technology system, the Health Plan Management System (HPMS), for manufacturers to submit the Small Biotech Exception Information Collection Request Form."[10] Although CMS intends to launch this new automated tool by "mid-2023," if the tool is not developed in time, "CMS will accept responses to this ICR by mail . . . using a mailing address that CMS will provide in program instruction."[11]

CMS's proposal to require manufacturers to submit Small Biotech Exception requests through the HPMS system could cause unwanted complications and delays for the agency and the manufacturers submitting the Exception request. The Small Biotech Exception is intended for smaller manufacturers, many of whom may not have experience navigating the HPMS system. Further, we are concerned that the tool may be rigid in nature, and we advocate that CMS allow for a flexible approach. Finally, we share CMS's concern that the new automated tool may be delayed, and believe that such a delay will limit the amount of time that manufacturers have to familiarize themselves with the HPMS system before the Small Biotech Exception request is due.

Therefore, Incyte recommends that this new tool should be available to manufacturers at least 30 days before the Small Biotech Exception submission deadline. This will give smaller manufacturers an opportunity to become familiar with the HPMS system and the new automated tool. It also will give CMS and manufacturers an opportunity to resolve any questions or technical issues before Small Biotech Exception requests are due. We also request that CMS provide manufacturers with a specified point of contact at the agency who has been trained on the new tool and can help manufacturers navigate the submission process.
Additionally, we request that CMS provide manufacturers with the option to submit a Small Biotech Exception request by mail—regardless of whether the automated tool is delayed. This flexibility would reduce burdens on

[7] 88 Fed. Reg. 4184-4185 ("The Information Collection Request Form for the Small Biotech Exception must be submitted to CMS before CMS establishes the selected drug list of initial price applicability year 2026").
[8] Small Biotech Exception Information Collection Request, Supporting Statement – Part A, at 3 "A Submitting Manufacturer is expected to submit the information only once for each drug for which the Submitting Manufacturer seeks the Small Biotech Exception"); *id.* at 5 (CMS estimates "10 total respondents in 2023").
[9] 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, Section 30.2.1
[10] Small Biotech Exception Information Collection Request (CMS-10844, OMB 0938-NEW), Supporting Statement – A, at 2.
[11] *Id.*

smaller manufacturers, who may not have direct experience navigating the HPMS system. Because CMS expects only 10 respondents in 2023, we do not anticipate that receiving paper submissions would significantly increase CMS' administrative burden.

III. CMS Should Clarify the "New Formulations" Provision of the Small Biotech Exception

Under the IRA, a "small biotech drug" is a "qualifying single source drug" that meets certain criteria generally related to Medicare total expenditures.[12] The IRA further specifies that "[a] new formulation, such as an extended release formulation, of a qualifying single source drug shall not be considered a [small biotech drug]."[13] However, neither the Medicare Drug Price Negotiation Program guidance nor this Small Biotech Exception ICR address how CMS interprets the "new formulation" provision with respect to the Small Biotech Exception.

Contrary to the statute,[14] the Medicare Drug Price Negotiation Program guidance adopts an expansive interpretation of a "qualifying single source drug." For a drug approved under a new drug application (NDA),[15] the guidance states, in relevant part, that a "qualifying single source drug" includes "all dosage forms and strengths with the same active moiety and the same holder of a [NDA], inclusive of products that are marketed pursuant to different NDAs."[16] To determine whether a drug meets the seven year threshold, CMS "intends to use the earliest date of approval . . . of the initial FDA application number assigned to the [NDA] holder for the [active moiety] . . . ."[17] Therefore, under CMS's interpretation, it appears that as long as one NDA was approved at least seven years before the selected drug publication date, approvals under any NDA would be part of the same "qualifying single source drug," as long as each product has the same active moiety and NDA holder. **Incyte strongly disagrees with CMS's interpretation of a qualifying single source drug, which goes beyond extended-release formulations. We also are concerned that CMS is not accepting comments on the "qualifying single source drug" definition, the Small Biotech Exception, and other foundational issues in Section 30 of the Medicare Drug Price Negotiation Program guidance related to how CMS will identify drugs for selection.**

As Incyte has previously communicated with CMS, ruxolitinib is the active pharmaceutical ingredient in two separate drugs that are marketed by Incyte, Jakafi and Opzelura™ (ruxolitinib) cream. Opzelura has no overlapping approved indications in common with Jakafi in whole or in part. Opzelura is FDA-approved for these two indications: (1) "the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable"; and (2) "the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older." See Opzelura Prescribing Information.

For a number of reasons, including those listed below, Incyte believes that Opzelura is not a "new formulation" of Jakafi. Opzelura, compared to Jakafi, is:

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[12] Specifically, a Part D drug is a "small biotech drug" if in 2021, the "total expenditures for the qualifying single source drug" were: (a) equal to or less than one percent of total expenditures under Part D for all covered Part D drugs; and (b) equal to at least 80 percent of total expenditures for all of the manufacturer's covered Part D drugs. SSA 1192(d)(2)(A).

[13] SSA 1192(d)(2)(C).

[14] The statute limits a "qualifying single source drug" to approvals under a single new drug application (NDA) or biologics license application (BLA). In relevant part for a drug approved under a NDA, the IRA defines a "qualifying single source drug" as a drug "that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act" and "for which, as of the selected drug publication date . . . at least 7 years will have elapsed since the date of such approval."[14] SSA § 1192(e)(1)(A) (emphasis added).

[15] CMS adopts a similar definition of a "qualifying single source drug" for biological products.

[16] 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, Section 30.1.

[17] *Id.*

- indicated to treat entirely different conditions in a different therapeutic area—dermatological vs. antineoplastic indications—with no overlap;
- supported by different safety and efficacy data developed specifically in relation to the new topical drug;
- not interchangeable—oral tablet Jakafi cannot be used to treat eczema, and topical Opzelura cannot be used to treat any of Jakafi's oncological indications;
- an entirely different dosage form—topical cream applied to the skin compared to an oral tablet;
- the subject of a separate New Drug Application (NDA) (not a supplemental NDA) supported by an array of human studies, including multiple, large Phase III clinical studies;
- sold under its own trade name and standalone labeling; and covered by new patents that Incyte obtained based on its innovation in creating new treatments in an entirely different therapeutic area.

If CMS nonetheless retains this interpretation of a "qualifying single source drug," we recommend that CMS clarify how the "new formulations" provision of the Small Biotech Exception fits within its broader interpretive framework. The Medicare Drug Price Negotiation Program guidance is premised on the idea that all dosage forms, strengths, and formulations of a qualifying single source drug will be treated in the same manner at every stage of the Program—including "applying the exception for small biotech drugs"[18]—as well as selection, determining the maximum fair price, and removal from the selected drug list. Consistent with the broader statutory text (and aligning with CMS's current interpretation of "qualifying single source drug"), we believe the best reading of the new formulations provision is that it serves as a clarification that a new formulation *on its own* may not meet the definition of a "small biotech drug." Rather, it must be aggregated with any other formulations that satisfy the "qualifying single source drug" definition. An alternative read—that new formulations must be carved out of a "qualifying single source drug" that meets the "small biotech drug" definition—would be in direct conflict with the Use of Data provision[19] applicable to the small biotech drug determination and impractical to implement. For example, it is unclear how CMS would treat a qualifying single source drug, if one portion of the qualifying single source drug was subject to the Small Biotech Exception, while another portion (i.e., new formulation(s)) were not subject to the Small Biotech Exception.

Incyte requests that CMS issue draft guidance clarifying how the Agency interprets the new formulations provision of the Small Biotech Exception. CMS should solicit public comments on the draft guidance before issuing final guidance on the new formulations provision.

IV. CMS Should Clarify Data Elements Included on the Small Biotech Form

a. Question 2 – Clarification on Scope of 11-digit National Drug Codes that Manufacturers Must Submit for Small Biotech Exception

As noted above, the IRA's exception for small biotech drugs excludes certain "qualifying single source drug[s]" (QSSDs) from being considered a "negotiation-eligible drug" in 2026, 2027, and 2028.[20]

The Small Biotech Exception Information Collection Request Form requires manufacturers to submit NDCs to CMS as a part of the small biotech exception determination process. Specifically, the form states:

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[18] 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, Section 30.1.

[19] The Use of Data provision states that "[i]n determining whether a qualifying single source drug satisfies the criteria [for negotiation-eligible drugs] or [the Small Biotech Exception], the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type." SSA 1192(d)(3)(B).

[20] [1192(d)(2)]

Question 2: Please list all 11-digit National Drug Codes (NDCs) either (A) sold or marketed during 2021 or (B) end-dated prior to December 31, 2021 for the covered Part D drug for which the Submitting Manufacturer seeks the Small Biotech Exception.

In CMS's March 15 guidance on the Medicare Price Negotiation Program,[21] CMS defines a QSSD as, "… all dosage forms and strengths of drugs with the same active moiety and the same holder of New Drug Application…even if those different drug products are marketed under different NDAs…."

Given CMS's definition of QSSD in the March 15 guidance, Incyte seeks clarity as to the scope of NDC-11s that CMS requires that manufacturers submit on question 2 of the Small Biotech Exception Information Collection Request Form.

Incyte is reviewing the March 15 guidance, including the implications of CMS's definition of QSSD and how, when Jakafi qualifies as a small biotech drug, Opzelura may be impacted. Based on this review, Incyte may provide additional comments to the Agency. In the meantime, Incyte asks CMS to confirm that we will only need to submit NDC-11s only for Jakafi on the Small Biotech Exception Information Collection Request Form and will not need to submit NDC-11s for Opzelura in order for our small biotech exception submission to be considered complete by the Agency.

b. Question 4—Specify that Manufacturers Should Submit Controlled Group Information Only for Those Entities Which Had a Coverage Gap Discount Program Agreement with CMS

The Small Biotech Exception statute includes an "Aggregation Rule," which states that "[a]ll persons treated as a single employer under section (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer" for purposes of determining whether the Small Biotech Exception applies (all persons are treated as part of the same "controlled group").[22] The ICR proposes the following questions to collect information from the relevant members of a controlled group treated as one "manufacturer" of a prospective small biotech drug, under the Aggregation Rule:

Question 4: Did the entity that had a Coverage Gap Discount Program agreement effective on December 31, 2021, for the covered Part D drug for which the Submitting Manufacturer seeks the Small Biotech Exception (i.e., either the Submitting Manufacturer or the entity identified in Question 3b, as applicable) have other members in its controlled group as of 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 4a: 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 covered Part D drug which the Submitting Manufacturer seeks the Small Biotech Exception.

[21] 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
[22] SSA 1192(d)(2)(B)(i).

For each member of the entity's controlled group, the ICR proposes that the Submitting Manufacturer would be required to report the following data elements: (a) entity name; (b) employer identification number(s) (EIN(s)); (c) address; (d) unique identifier assigned by CMS (P-number); and (e) labeler code(s).

Incyte recommends that CMS revise Question 4a to remove ambiguity, as that question could be subject to multiple interpretations. In particular, it is unclear whether the clause "that had the Coverage Gap Discount Agreement effective on December 31, 2021" modifies: (a) "the entity"; or (b) "each such member of the controlled group." We believe that CMS's intent is the latter such that a Submitting Manufacturer would be required to report the requested data elements only for members of the controlled group that had a Coverage Gap Discount Agreement effective on December 31, 2021. This interpretation is consistent with the statutory criteria for a small biotech drug, which is based on the total Medicare expenditures of a manufacturer in 2021. It is also consistent with the requirement to report the P-number for each member of the entity's controlled group, because only members with Coverage Gap Discount Agreements would have a P-number. Generally, if a member of the controlled group did not have a Coverage Gap Discount Agreement effective December 31, 2021, it would not have had any Part D expenditures in 2021. Alternatively, however, we believe that Question 4a could be read to require a Submitting Manufacturer to report on *all* members of the controlled group, even those that did not have a Coverage Gap Discount Agreement effective on December 31, 2021. Such alternative reading would increase burdens for manufacturers, who would be required to report information that is not relevant to eligibility for the Small Biotech Exception. The inclusion of such irrelevant information also would increase the administrative burden of reviewing Small Biotech Exception requests. Finally, we are concerned that this ambiguity could lead a manufacturer to submit information the Agency considers incomplete. As outlined in Section 30.2.1 of the Medicare Drug Price Negotiation Program guidance, CMS states that it "does not plan to consider incomplete submissions."[23]

Therefore, we recommend that CMS revise question 4a to make clear that a Submitting Manufacturer is only required to report information on members of the controlled group if the member had a Coverage Gap Discount Program agreement effective on December 31, 2021. Specifically, Incyte recommends that CMS align the language in question 4a with the corresponding question from the Medicare Part D Manufacturer Discount Program Agreement ICR (Part D Discount Program ICR).[24] The Small Biotech Exception and the Part D Discount Program's protections for "specified small manufacturers"[25] include nearly identical Aggregation Rules. However, the proposed Small Biotech Exception ICR and the proposed Part D Discount Program ICR do not include the same question(s) to collect information relevant to the each program's Aggregation Rule. Incyte believes that the phrasing in the Part D Discount Program ICR's question on the Aggregation Rule more clearly articulates that the Submitting Manufacturer is only required to report information on members of the controlled group that had a Coverage Gap Discount Program agreement effective on December 31, 2021. In relevant part, the Part D Discount Program ICR states:

> Did the submitting Manufacturer have a Coverage Gap Discount Program Agreement under 42 USC § 1395w-114a effective on December 31, 2021 AND have any other corporation or business (whether or not incorporated) in its controlled group, as of December 31, 2021, that had a Coverage Gap Discount Program Agreement under 42 USC § 1395w-114a effective on December 31, 2021? For the purpose of this information collection request, "controlled group" means all corporations

[23] 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, Section 30.2.1

[24] 88 Fed. Reg. 7976 (Feb. 7, 2023).

[25] SSA 1860D-14B(g)(4)(C)(ii)(II)(bb) ("All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this subparagraph. For purposes of making a determination pursuant to the previous sentence, an agreement under this section shall require that a manufacturer provide and attest to such information as specified by the Secretary as necessary.").

> or partnerships, proprietorships and other entities treated as a single employer under 26 U.S. Code sehction 52(a) or (b). Y/N[26]

For each member of the entity's controlled group, the Part D Discount Program's ICR proposes that the Submitting Manufacturer would be required to report the same data elements as the Small Biotech Exception ICR: (a) entity name; (b) employer identification number(s) (EIN(s)); (c) address; (d) unique identifier assigned by CMS (P-number); and (e) labeler code(s).

Therefore, to improve clarity, remove ambiguity, and align both ICRs, Incyte requests that CMS replace question 4 and question 4a on the Small Biotech Exception ICR with the above question from the proposed Part D Discount Program ICR.

c. Limit the Certification to the Intended Use of this ICR— Eligibility for the Small Biotech Exception under the Program

In the section justifying the "Need and Legal Basis" for this ICR, CMS states that "[t]his information is required in order for CMS to accurately identify whether a given drug meets the criteria for the Small Biotech Exception in accordance with section 1192(d)(2) of the Act."[27] The certification that the Submitting Manufacturer is required to complete, however, is much broader than CMS's stated need for this ICR. In relevant part, the certification states the following:

> 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 covered Part D drug of the Submitting Manufacturer qualifies for the Small Biotech Exception, as described in section 1192(d)(2) of the Social Security Act.[28]

First, the certification states that the information will be used "for Medicare reimbursement purposes," even though the Small Biotech Exception is only relevant under the Program—not Medicare, more broadly. [29] Additionally, the use of the word "including" could be interpreted to permit CMS to use information collected under this ICR for purposes other than eligibility for the Small Biotech Exception. Incyte believes that CMS should closely align the certification with the Agency's stated need for this ICR. Therefore, we recommend revising the ICR's certification to read as follows:

> I understand the information contained in this submission is being provided to and will be relied upon by CMS for ~~Medicare reimbursement~~ purposes of the program under part E of Title XI of the Social Security Act~~,~~; ~~including~~ specifically, for CMS to determine whether the covered Part D drug of the Submitting Manufacturer qualifies for the Small Biotech Exception, as described in section 1192(d)(2) of the Social Security Act.

We believe this proposed revision reflects the ICR's justification—to determine whether a drug qualifies for the Small Biotech Exception under the Program.

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[26] Medicare Part D Manufacturer Discount Program Agreement; Appendix A, Proposed Part D Manufacturer Discount Program (MDP) Data Entry Fields in HPMS at 4.
[27] Small Biotech ICR Form (CMS 10844, OMB 0938-NEW) at 2.
[28] *Id.* at 4 (emphasis added).
[29] *Id.*

Incyte appreciates the opportunity to comment on this Information Collection Request on the Small Biotech Exception. We hope that CMS consider the suggestions and clarifications outlined above. We would welcome the opportunity to meet with you or answer any questions CMS may have about our comments, at your request. Thank you.

Sincerely,

Barry Flannelly
Executive Vice President & General Manager
North America