

INSTRUCTIONS FOR FILLING OUT FORM FDA 3988 TRANSMITTAL OF PMR/PMC SUBMISSIONS FOR DRUGS AND BIOLOGICAL PRODUCTS

(The field numbers below correspond to the numbered boxes on the Form FDA 3988)

Complete this form to accompany all postmarketing requirement (PMR) and postmarketing commitment (PMC)-related submissions to original and supplemental New Drug Applications (NDA, sNDA) and Biologics License Applications (BLA, sBLA), Abbreviated New Drug Applications (ANDAs), and Investigational New Drug (IND) applications (final and draft protocol submissions).

This form does not replace [Form FDA 356h](#). You are still expected to submit Form FDA 356h with submissions to your original and supplemental NDA, ANDA, and BLA as applicable.

Exceptions

- This form is not intended to accompany an Annual Status Report (ASR) submission required under 21 CFR 314.81 or 601.70 or to accompany [Form FDA 3989](#), “PMR/PMC Annual Status Report for Drugs and Biological Products.”
- You should not include this form with cross-reference letters. For example, Form FDA 3988 should accompany a clinical protocol submitted to the IND but should not be submitted with the corresponding cross-reference letters submitted to the marketing application referencing the protocol.

FIELD 1: CENTER

Check only one box indicating the Center that approved or licensed the application. CDER represents the Center for Drug Evaluation and Research. CBER represents the Center for Biologics Evaluation and Research.

FIELD 2: DATE OF SUBMISSION

Enter the date on which you are submitting this form to the FDA. The date entered should match the date on the cover letter accompanying this form (if applicable). Use the mm/dd/yyyy format.

FIELD 3: APPLICANT NAME

Enter the name of the applicant.^{1,2}

FIELD 4: APPLICATION TYPE

Select only one application type using the check box to the left of the type: NDA, BLA, ANDA, or IND

FIELD 5: APPLICATION NUMBER

Provide the six-digit application number. For application numbers less than six-digits, the application number should be preceded with zeros (e.g., instead of 12345, enter 012345). For BLAs, enter the six-digit application number/Submission Tracking Number (STN).

FIELD 6: SUPPLEMENT NUMBER(S)

For CDER-managed NDAs, ANDAs, and BLAs (as applicable): provide the four-digit supplement number(s) in which the PMR/PMC was established. For supplement numbers that are less than four-digits the supplement number should be preceded by zeros (e.g., for Supplement 1 enter 0001). If you enter more than one supplement number, separate each with a comma.

For CBER managed applications, enter the four-digit application number/Secondary STN (as applicable).

¹ For NDAs and ANDAs, in accordance with 21 CFR 314.3, *Applicant* is any person who submits an NDA (including a 505(b)(2) application) or ANDA or an amendment or supplement to an NDA or ANDA under this part to obtain FDA approval of a new drug and any person who owns an approved NDA (including a 505(b)(2) application) or ANDA.

² For BLAs, the name of the applicant is the name of the person or legal entity to which the license has been issued.

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FIELD 7: ESTABLISHED NAME

Provide the established name for the approved drug product (in the case of a licensed biological product, the proper name), such as the United States Pharmacopeia (USP) or United States Adopted Name (USAN) name.

FIELD 8: PROPRIETARY NAME(S)

Provide the proprietary name (trade name), if any.

SECTION 9: PMR/PMC INFORMATION

Enter information for all PMRs/PMCs addressed in the accompanying submission. If you are entering information for more than three PMRs/PMCs, complete the fields for the first three PMRs/PMCs, then select the “Add Row” button at the bottom of this section to enter information about the next PMR or PMC.

Field – Type

Select either PMR or PMC from the drop-down list, as applicable.

Field – PMR or PMC Number

Indicate the PMR or PMC number using the Center-specific format.

- For CDER-managed PMRs and PMCs, use the XXXX-XX format (for instance, 1234-10).
- For CBER-managed PMRs and PMCs insert: “STN XXXXX/XXXX PMR/PMC # (e.g., STN 12345/5463 PMC 1).

Field – Establishment Date

Enter the establishment date. The establishment date is the date of the letter in which the final PMR or PMC was first communicated, usually an approval letter or a post-approval Acknowledge New PMR/PMC letter. Use the mm/dd/yyyy format.

Field – National Clinical Trial (NCT) Number (if applicable)

- Enter the NCT Number(s), as applicable. If you have more than one NCT number related to a PMR/PMC, you may instead indicate that you are adding a list to this form.
- Use the format: NCT XXXXXXX. Refer to [Form FDA 3674](#) “Certification of Compliance, under 42 U.S.C., 282(j)(5)(B), with Requirements of ClinicalTrials.gov” and the accompanying [Form FDA 3674 instructions](#).

BUTTONS

Add Row

Located below section 9, clicking on this button will add another row to section 9 allowing you to add information for another PMR or PMC. You can add additional rows by repeatedly clicking on this button.

Remove Last Row

Located to the right of the “Add Row” button, clicking on this button will remove the last row of section 9 fields that were most recently added.

FIELD 10: PMR/PMC SUBMISSION TYPE

Check all the document types you are submitting with this form.

- “**Draft Protocol**” or “**Final Protocol**” refers to either a draft or final version of a study or clinical trial protocol related to a PMR or PMC. Provide the application number on the line provided using the format: ##### (see instructions for Field 5).
 - Submit clinical protocols to your IND with a cross-reference letter to the appropriate marketing application (see information cross-reference letters in the first section of this form).
 - Submit nonclinical and chemistry, manufacturing, and controls protocols to your application.
 - Although you may indicate that your submission is the “final protocol,” the FDA will not consider a protocol “final” until FDA has reviewed and fully concurred with the submitted protocol.

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- **“Interim Report”** refers to reports that are submitted, usually annually, during the course of a study or trial. Interim reports may be required as PMR/PMC milestones.
- **“Final Report”** refers to a summary report providing information intended to complete a PMR or PMC. The appropriate FDA division will review the report to determine if the requirement or commitment has been fulfilled. Submit all final reports to the appropriate marketing application.
- **“General Correspondence”** refers to PMR/PMC-related submissions that do not fall into the other categories listed in Field 10. For example, general correspondence may include questions related to the PMR/PMC study design, requests for release from a PMR/PMC, or updates on the progress of a study/trial.
- **“PREA PMR³ Deferral Extension Request”** refers to requests to extend the deferral date (i.e., deferred due date) for studies required under section 505B of the Federal Food, Drug, and Cosmetic Act (often referred to as the Pediatric Research Equity Act, or PREA). The deferral date refers only to the final report submission due date. Submit all final reports to the appropriate original or supplemental marketing application.
- **“Response to Information Request”** refers to a submission responding to FDA’s request for information about a PMR or PMC.
- **“Request for Revised Milestones”** refers to a submission requesting that FDA consider proposed revised milestone date(s). For 505(o)(3) PMRs, ensure that the submission accompanying this form identifies the type of revised milestone(s) being requested by adding the appropriate heading to the cover letter: **Notification of Failure to Meet a PMR Milestone(s) Required Under Section 505(o)**” or **“Notification of Anticipated Failure to Meet a PMR Milestone(s) Required Under Section 505(o).”**
- **“Request for Release of PMR/PMC”** refers to submissions related to requests to release the applicant from the PMR or PMC or responses to additional information requests from FDA related to an applicant’s request for release of a PMR or PMC. Ensure that the submission accompanying this form clearly indicates in the cover letter: **“Release Request”** and indicate the related PMR/PMC set and number.
- **“Other”** refers to correspondence related to a PMR or PMC that does not fit into the other categories listed in Field 10 (e.g. specialized reports requested when the PMR/PMC was established).

FIELD 11: DESCRIPTION OF SUBMISSION CONTENT

Provide a brief explanation of the contents of, or rationale for, each document submitted with this form. For example:

- “to provide the final protocol for PMR [number] incorporating information from our recent communications with FDA,”
- “to provide the final report to fulfill PMR [number],”
- “general correspondence requesting a release from PMR [number] because....”

FIELD 12.a.: NAME AND TITLE OF APPLICANT’S RESPONSIBLE OFFICIAL

The “Responsible Official” is the person responsible for certifying compliance with applicable laws and regulations. An authorized United States (U.S.) agent may also act as the applicant’s Responsible Official. The form must be signed in **Field 17.a.** by the applicant, or the applicant’s attorney, agent, or other authorized official. [21. CFR 314.50(a)(5); 21 CFR 601.2(a)]

If the person signing the form in **Field 17.a.** does not reside or have a place of business within the U.S., the form must be countersigned in **Field 17.b.** by an attorney, agent, or other authorized official who resides or maintains a place of business within the U.S. [21 CFR 314.50(a)(5) and 601.2(a)].

FIELD 12.b. DATE

Enter the date that this form is signed using the mm/dd/yyyy format.

FIELDS 13–15: TELEPHONE NUMBER, FAX NUMBER, AND EMAIL ADDRESS

As applicable, provide the telephone number, facsimile number, and email address in each of the corresponding fields for the applicant’s Responsible Official.

³ A PREA PMR is a deferred pediatric study requirement that is issued as a PMR at the time of the approval of the drug or biological product.

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FIELD 16: ADDRESS OF APPLICANT'S RESPONSIBLE OFFICIAL

Provide the address for the applicant's Responsible Official.

FIELD 17.a.: SIGNATURE OF APPLICANT'S RESPONSIBLE OFFICIAL OR OTHER AUTHORIZED OFFICIAL

See the description of the Responsible Official and other authorized official offered in **Field 12.a.** to determine who should sign in this field.

FIELD 17.b.: COUNTERSIGNATURE OF AUTHORIZED U.S. AGENT

As stated for Field 12.a., if the person signing the form in **Field 17.a.** does not reside or have a place of business within the U.S., this form must be countersigned in this field by an attorney, agent, or other authorized official who resides or maintains a place of business within the U.S. [21 CFR 314.50(a)(5)].

BUTTONS: SIGN

Located on the right side of field 17.a. Once all mandated fields are completed, clicking on this button will open an electronic signature field in fields 17.a. and 17.b.