DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

INSTRUCTIONS FOR FILLING OUT FORM FDA 3989 PMR/PMC ANNUAL STATUS REPORT FOR DRUGS AND BIOLOGICAL PRODUCTS

(The field numbers below correspond to the numbered boxes on Form FDA 3989)

Use this form to report annually on all open postmarketing requirements (PMRs) and postmarketing commitments (PMCs) as required by 21 CFR 314.81(b)(2)(vii) and 601.70. Submitting this form will fulfill your annual PMR/PMC reporting obligations for New Drug Applications (NDA), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLA).

- **NDAs and ANDAs:**
  - Complete and submit this form in the electronic Common Technical Document's (eCTD's) module 1, section 1.13.12, "Status of Postmarketing Commitments and Requirements"[1] instead of submitting a company-derived PMR/PMC status update in this section.
  - *Do not use this form* to provide information on the "Status of Other Postmarketing Studies and Requirements" as required by 21 CFR 314.81(b)(2)(viii). You must still provide this information in section 1.13.13 of your Annual Report (AR).
- **BLAs:**
  - Complete and submit this form instead of your annual report on PMRs and PMCs as required by 21 CFR 601.70.
- **Form FDA 2252:**
  - This *form* does not replace Form FDA 2252 (TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS AND BIOLOGICAL PRODUCTS FOR HUMAN USE). Form FDA 2252 *should accompany all* NDA and BLA annual report submissions.
  - In Form FDA 2252, *section* 9.g. "Status Reports of Postmarketing Commitments," indicate that you used this form to report on the annual status of your PMRs and PMCs. For instance, in section 9.g., note: "Refer to Form FDA 3989."
- **Additional Information:**

  Refer to the guidance below regarding the content to be provided in the PMR/PMC annual status update: February 2006 Guidance for Industry: Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997.[2]

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 of the cover letter (as applicable) accompanying this form. Use the mm/dd/yyyy format.

FIELD 3: APPLICANT NAME

Enter the name of the applicant.[3,4]

[1] Refers to Module 1 (Administrative Information); Section 13 (Annual Report), Subsection 12 (Status of Postmarketing Commitments and Requirements)

[2] We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[3] 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.

[4] For BLAs, the name of the applicant in this field is the name of the person or legal entity to which the license has been issued.

FIELD 4: APPLICATION TYPE

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

(continued on next page)

FIELD 5: APPLICATION NUMBER

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

FIELD 6: 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 7: PROPRIETARY NAME(S)

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

FIELD 8: DATE OF U.S. APPROVAL

Enter the date the NDA, ANDA, or BLA was approved or licensed by the FDA, for example, the date on the FDA approval letter issued to an applicant for an NDA.[5] Use the mm/dd/yyyy format.

FIELD 9: ALTERNATE ANNUAL STATUS REPORT DUE DATE

This is a date, other than the approval date, that the FDA has allowed the applicant to use for annual reporting. This alternate date must be granted formally by FDA in response to a waiver request (e.g., a harmonized or combined AR due date).

FIELD 10: PERIOD COVERED BY REPORT

Enter the year (yyyy) and month (mm) that reflects the current reporting period using the format conveyed above. Although helpful, this field is optional.

SECTION 11: PMR/PMC UPDATE

Repeat this Section for each PMR or PMC. Use the “Add Item 11” button as described below to add fields 11.a. through 11.j. for each additional PMR or PMC. You are only required to report on open PMRs and PMCs (see section 11.g.)

FIELD 11.a.: PMR/PMC NUMBER

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

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

FIELD 11.b.: PMR/PMC 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 11.c.: SUPPLEMENT NUMBER

As applicable, provide the four-digit supplement number preceded by the original application number, in which the PMR/PMC was established.

FIELD 11.d.: STUDY/TRIAL TITLE

If applicable, enter the name of the study or clinical trial.

You may also include in this field, the purpose of the study/trial, the type of study/trial, the patient population addressed and the indication(s) and dosage(s) that are being studied.

[5] The date of approval is the date on the approval letter from FDA stating that the NDA is approved, except that the date of approval for an NDA described in section 505(x)(1) of the Federal Food, Drug, and Cosmetic Act is determined as described in section 505(x)(2) of the Federal Food, Drug, and Cosmetic Act. “Date of approval” refers only to a final approval and not to a tentative approval. (see 21 CFR 314.3)

Because registration information is required for clinical trials under section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act, add the NCT number to this field if available or complete Form FDA 3674 "Certification of Compliance, under 42 U.S.C. 282(j)(5)(B) with Requirements of ClinicalTrials.gov" and submit a copy with Form FDA 3989.[6]

FIELD 11.e.: PMR/PMC DESCRIPTION

Enter the PMR or PMC description communicated in the letter that established the PMR or PMC (usually the Approval letter or post-approval Acknowledge New PMR/PMC letter).

FIELD 11.f. CURRENT ENROLLMENT

Except for studies/trials that have not yet begun (e.g., those in pending status) or non-clinical studies, you should enter the number of subjects enrolled to date (as the numerator) and the total number of expected subjects to be enrolled (as the denominator). For example, indicate 50 subjects enrolled to date of 100 subjects expected to be enrolled as: "50/100."

FIELD 11.g. STUDY/TRIAL STATUS

Select the current open status of the PMR/PMC using one of the following terms from the drop-down list that describes the study/trial status for this annual reporting period. The status is based on the original timetable unless a deferral extension has been granted to a PREA PMR[7] (required under section 505B of the Federal Food, Drug, and Cosmetic Act, often referred to as the Pediatric Research Equity Act, or PREA) for the final report submission due date.

Open Statuses

- Pending: The study/trial has not been initiated and does not meet the criterion for delayed. In other words, no subjects have been enrolled or animals dosed; however, the original date for initiation of patient accrual or initiation of animal dosing *has not* passed.
- Ongoing: The study/trial is proceeding according to or ahead of the original schedule as described in 21 CFR 314.81(b)(2)(vii)*(a)(8)* and 601.70(b)(8). The FDA considers the study/trial to be ongoing until a final report is submitted to the FDA, as long as the activities are proceeding according to the *original* schedule.
    - If patient accrual or animal dosing has started but is not complete, and the projected date for completion of that milestone has passed, the study/trial should be categorized as *delayed*.
- Delayed: The study/trial is behind the *original* schedule as described in 21 CFR 314.81(b)(2)(vii)*(a)(8)* and 601.70(b)(8). Delays can occur in any phase of the study/trial, including patient enrollment, analysis of results, or submission of the final report to the FDA.
    - Although the original study/trial schedule, not a revised schedule, serves as the basis for defining a study/trial as delayed, each phase of the study/trial will be considered in its own right. If the applicant has one delayed phase but gets back on schedule during the next phase (e.g., meets the next milestone due date), the delayed status will no longer apply.
- Submitted: The study/trial has been completed or terminated and a final report has been submitted to FDA. FDA has not yet notified the applicant in writing that the PMR/PMC has been fulfilled or released.
- Terminated: The study/trial was ended before completion, but a final report has not been submitted to FDA.

Closed Statuses (fulfilled or released): you do not need to provide an update for those PMRs or PMCs that have closed since your last annual status report.

[6] See the guidance for sponsors, industry, researchers, investigators, and FDA staff Form FDA 3674 — Certifications to Accompany Drug, Biological Product, and Device Applications/Submissions (June 2017). Available at https://www.fda.gov/media/134964/download

[7] 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.

FIELD 11.h.: EXPLANATION OF STATUS

Provide an explanation of the how the study/trial is progressing in reference to the *original* projected schedule (21 CFR 314.81(b)(2)(vii*)(a)(9)* and 601.70(b)(9)). The explanation of status will be displayed on the FDA's public Web page for studies and trials with a "delayed" or "terminated" status, and for all PREA PMRs; therefore, this statement should be concise and should not include confidential commercial or trade secret information.

FIELD 11.i.: MILESTONE INFORMATION

Enter the following information related to PMR/PMC milestones: Draft Protocol Submission, Final Protocol Submission, Study/Trial Completion, Final Report Submission, and as applicable, Interim Reports. In the corresponding fields, enter the *original* milestone dates and, if applicable, revised milestone dates. Use the mm/dd/yyyy format.

- **Fields 1.a., 2.a., 3.a., 4.a., and 5.a.: Milestone Type**
  - These fields list the core milestone types often required or agreed to when the PMR/PMC is established.
  - If one of the listed milestone types was not agreed to or required when the PMR/PMC was established, you should select the box "Check if not applicable." Do not leave the field blank. For example, if your PMR/PMC does not have a draft protocol submission milestone (1.a.), check the box. When this box is checked, you will not be able to enter dates into the related "Original Milestone" or "Revised Milestone" fields.
  - You can add other types of milestones (e.g., Interim Annual Report Submission) by using field 3.a. Add additional blank fields (field 3.a.) as needed (see instructions below under "Buttons").
- **Fields 1.b., 2.b., 3.b., 4.b., and 5.b.: Original Date**

  Provide the original milestone dates identified in the letter in which the PMR/PMC was established. Use the mm/dd/yyyy format. Leave blank if not applicable. You will not be able to enter a date into this field if you checked the "Check if not applicable" box in the related "Milestone Type" field.

- **Fields 1.c., 2.c., 3.c., 4.c., and 5.c.: Revised Date**
  - If you are including proposed revised milestone dates that have not been acknowledged by FDA, check the box, "Check if New." Provide a reason for the revised date in field 11.j.
  - If the revised milestone date was previously reported, and is unchanged since the last report, continue to report *both* the original and revised milestone dates, but *Do Not* check the box, "Check if New." Provide a reason for the revised date in field 11.j.
  - You will not be able to enter a date into this field if you checked the "Check if not applicable" box in the related "Milestone Type" field.
  - If you do not have anything to add to this field because it does not apply to the PMR/PMC, leave it blank.
  - Use the mm/dd/yyyy format.
- **Buttons:**
  - **Add Fields 11.i-3.a.-c.**: If you need to add additional milestones (e.g., a second Interim Report or other interim milestone), click the "Add Field 11.i.-3.a.-c." button located to the right of field 11.i.-3.c. Clicking this button will *add* an additional row for fields 11.i.-3.a., 11.i.-3.b., and 11.i.-3.c.
  - **Remove This Field 11.i-3.a.-c.**: If you need to remove the last row of milestones you added for 11.i.-3.a.-c., click the "Remove This Field 11.i-3.a.-c." button located to the right of the "Add Fields 11.i.-3.a-c." button. Clicking on this button allows you to *remove* fields 11.i.-3.a., 11.i.-3.b., and 11.i.-3.c. that were most recently added.

FIELD 11.j.: REVISED REASON

If you entered date(s) into the "Revised Date" field(s), provide the reason(s) for the requested revised dates (e.g., slow accrual). If your PMR/PMC is proceeding according to or ahead of the original schedule, and you have not requested revised dates, enter "not applicable" or "N/A."

Button: Add Second Section 11

Clicking on this button, located below field 11.j., will *add* an additional section 11 (fields 11.a. – 11.j.) to a new separate page, allowing you to add additional PMRs/PMCs to this form.

Separate Page Buttons: the buttons below will appear below field 11.j. on any new separate pages that were added.

- **Return to 12.a.**: Clicking this button will return the user to field 12.a. "Name and Title of Applicant's Responsible Official."
- **Add New Section 11**: Clicking this button will add another section 11 (fields 11.a. – 11.j.) to a new separate page, allowing you to add additional PMRs/PMCs to this form.
- **Delete this Section 11**: Clicking this button will remove only the section 11 fields on this page and will remove this separate page from the form. All pages will be renumbered as appropriate with the remaining pages.

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 U.S. agent may also act as the applicant's Responsible Official. The form must be signed in **Field 18**. 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 18**. does not reside or have a place of business within the United States (U.S.), the form must be countersigned in **Field 19**. 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)]

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.

FIELD 16: ADDRESS OF APPLICANT'S RESPONSIBLE OFFICIAL

Provide the address for the applicant's Responsible Official (as defined above).

FIELD 17: ADDRESS OF AUTHORIZED U.S. AGENT

Provide the address for the Authorized U.S. Agent, if applicable. This field is required for non-U.S. applicants.

FIELD 18: 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 19: COUNTERSIGNATURE OF AUTHORIZED U.S. AGENT

As stated under **Field 12.a.**, if the person signing the form in **Field 18**. 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 another authorized official who resides or maintains a place of business with the U.S. [21 CFR 314.50(a)(5)].

Button: Sign

Located on the right side of **Field 18**. Once all mandated fields are completed, clicking on this button will open electronic signature fields in fields 18 and 19.