OMB Control No. 0910-0001 – ATTACHMENT A

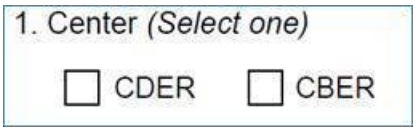
Proposed Changes to Associated Forms FDA 2252 and 2253

Changes to Form FDA 2252 – *Transmittal of Annual Reports for Drugs and Biologics for Human Use*

Form FDA 2252 should accompany annual reports for new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) as required in 21 Code of Federal Regulations (CFR) 314.81 and 21 United States Code (USC) 355. In advance of updates to be implemented for submission of the forms and accompanying documentation early in calendar year 2021, the Center for Drug Evaluation and Research (CDER) and the Center for Biologic Evaluation and Research (CBER) recommend an update of the form to improve efficiency in collecting and using the data. The form is available for electronic submission. Minor database changes are being implemented as noted below.

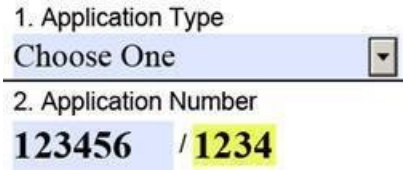
A. Form FDA 2252 Revisions (Draft Form FDA 2252 with revisions is attached):

1. Remove the "APPLICANT NOTE: Reference NDA and Y, or BLA numbers (entered on Acknowledgement Copy) in any subsequent correspondence regarding report."
2. Add a new mandatory field, "**1. Center (Select one)**" using the example below and existing formats from FDA Form 2252.



Field numbering will also require adjustment throughout the entire form.

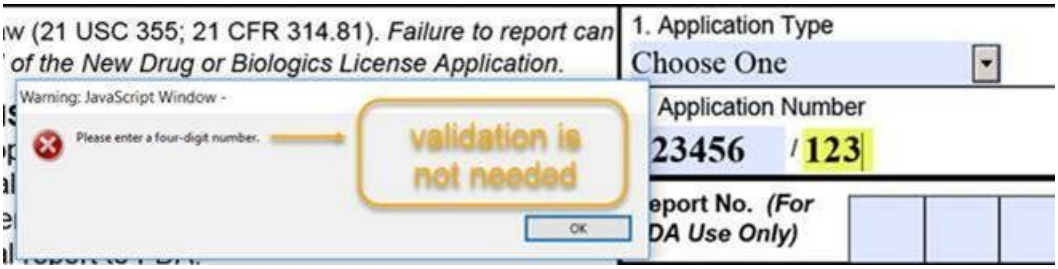
3. Application number field (currently available on the form) should allow for an additional 4 digit number following the application number to identify supplemental application submissions.



The "Center" field selection should drive the appearance of the Application Number (see highlighted below) as follows:

- If **CDER** is selected, the 4 digit part of the Application Number should be **hidden**
- If **CBER** is selected, the 4 digit part of the Application Number should be **available,** but is not mandatory

4. Remove the current validation for the 4 digit part of the Application Number entry. The field should accept one, two, three, or four digit numeric values as well as blanks, but no other characters or special symbols.



5. Revise field 9. by Replacing "STATUS REPORTS OF OPEN PMRS/PMCS *(leave blank if no open PMRs/PMCs to report)*" with "g. STATUS REPORTS OF OPEN PMRs/PMCs *(enter None if no open PMRs/PMCs to report)*".

6. Renumber the fields accordingly, i.e. "1. Application Type" should become "2. Application Type", "2. Application Number" will become "3. Application Number", etc.

7. Since field 7 will become field 8, also replace "If any part of the annual report applies to more than one application, list in item 7 all other applications to which such parts apply." with "If any part of the annual report applies to more than one application, list in item 8 all other applications to which such parts apply."

8. Since field 9 will become field 10, also replace (INFORMATION IN "9b" AND "9c" IS ALWAYS REQUIRED.) with (INFORMATION IN "10b" AND "10c" IS ALWAYS REQUIRED.)

B. Form FDA 2252 Revisions to **Instruction Supplement**

1. Add "Field 1. Select appropriate Center" after the Note on top of page 1

2. Replace "For CBER BLAs enter the supplement number, if known." with "For CBER submissions, both the application and the supplement number, as applicable, should be entered."

3. Replace "Leave this field blank if you have no "open" PMRs or 506B Reportable PMCs to report." with "Enter None if you have no "open" PMRs or 506B Reportable PMCs to report." in Field 9 g. Status Reports of Open PMRs/PMCs

4. Replace "Leave this field blank if you have no "open" CMC postmarketing studies to report." with "Enter None if you have no "open" CMC postmarketing studies to report." in Field 9 h. Status of Other Open Postmarketing Studies

5. Renumber all fields including references throughout the text as specified in attached document, **2252_instructions_508 changes requested on 12.22.2020.docx**. Note that the document also includes the changes requested above for a better visual representation.

Changes to Form FDA 2253 – *Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use*

Form FDA 2253 should accompany submissions of Advertisements and Promotional Labeling for new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) as required in 21 Code of Federal Regulations (CFR) 314.81, 21 CFR 601.12, 21 United States Code (USC) 355, and Section 351 of the Public Health Service Act.

In advance of updates to be implemented for submission of the forms and accompanying documentation early in calendar year 2021, the Center for Drug Evaluation and Research (CDER) and the Center for Biologic Evaluation and Research (CBER) recommend an update of the form to improve efficiency in collecting and using the data. The form is available for electronic submission. Minor database changes are being implemented as noted below.

A. Form FDA 2253 Revisions (Draft Form FDA 2253 with revisions is attached):

1. Replace **NOTE: Form FDA 2253 is required by law. Reports are required for approved NDAs and ANDAs (21 CFR 314.81).** with

   "**NOTE: Form FDA 2253 is required by law. Reports are required for approved NDAs, ANDAs (21 CFR 314.81), and BLAs (601.12(f)(4))**.

2. Remove "AADA" from the Application Type drop-down list

3. Add an optional 4 digit part of the Application Number after the current 6 digit number

B. Instructions for Form FDA 2253

1. Remove "2. **Label Review Number –** If applicable, provide the previously assigned label review number from Form FDA 2567 "Transmittal of Labels and Circulars Form." and re-number the rest of the list accordingly, i.e. **Application Information** would become 2., **Proprietary Name** would become 3., etc.

2. Replace current **Application Information** description with:
   "**Application Information –** Provide the application type (New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Biologics License Application (BLA), Premarket Approval Application (PMA)) from the drop-down followed by the application number. For CBER BLAs enter the supplement number, if known. "