Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
APS Caseworker Focus Group	84	1	1.5	126
APS Leaders Interview	16	1	1	16
Total	12,124		3.58	2,164

Dated: August 14, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–17879 Filed 8–19–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0411]

Bristol-Myers Squibb Co. et al.; Withdrawal of Approval of 70 New Drug Applications and 97 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 8, 2011. The document announced the withdrawal of approval of 70 new drug applications (NDAs) and 97 abbreviated new drug applications from multiple applicants, effective July 8, 2011. The document contained the incorrect applicant information for NDA 018380. The correct applicant for NDA 018380 is Hospira, Inc. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, June 8, 2011 (76 FR 33310), appearing on page 33310 in FR Doc. 2011–14164, the following correction is made:

On page 33311, in table 1, in the ''Applicant'' column for NDA 018380, correct the entry ''Do.'' to read ''Hospira, Inc., 275 North Field Dr., Bldg. H2, Lake Forest, IL 60045–5046.''

Dated: August 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17933 Filed 8–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3500]

Fit for Use Pilot Program Invitation for the Clinical Data Interchange Standards Consortium for Standard for Exchange of Nonclinical Data Implementation Guide: Version 3.1

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it intends to conduct a Fit for Use (FFU) pilot program to test the processing and analysis of nonclinical study data provided electronically for the Clinical Data Interchange Standards Consortium (CDISC) for Standard for Exchange of Nonclinical Data (SEND) Implementation Guide (IG): Version 3.1 (SEND 3.1). The Agency's Center for Drug Evaluation and Research (CDER) will test the processing and analysis of nonclinical study data provided electronically in SEND 3.1 format. FDA is inviting individual firms that wish to participate in this pilot program to submit participation requests via email or in writing.

DATES: To be considered for participation in the pilot program, submit electronic or written requests by September 19, 2019. See the **ADDRESSES** section for participation request instructions.

ADDRESSES: Submit electronic requests to participate in the pilot and comments regarding this pilot project to *https://www.regulations.gov.* Submit written requests to participate in the pilot and comments regarding the pilot to Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time by September 19, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–3500 for ''Fit for Use Pilot Program Invitation for the Clinical Data Interchange Standards Consortium for Standard for Exchange of Nonclinical Data Implementation Guide: Version 3.1.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will