TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
516.119; requires a foreign drug company to submit and update the name and address of a permanent U.S. resident agent	5	1	5	1	5
516.121; written request for a meeting with FDA to discuss the requirements for indexing a new animal drug	30	2	60	4	240
516.123; written request for an informal conference and a requestor's written response to an FDA initial decision denying a request	3	1	3	8	24
516.125; correspondence and information associated with investigational use of new animal drugs intended for indexing	2	3	6	20	120
516.129; content and format of a request for determination of eligibility for indexing	30	2	60	20	1,200
516.141; information to be submitted to FDA by a requestor seeking to establish a qualified expert panel	20	1	20	16	320
516.143; content and format of the written report of the qualified expert panel	20	1	20	120	2,400
516.145; content and format of a request for addition to the index	20	1	20	20	400
516.161; content and format of a request for modification of an indexed drug	3	1	3	4	12
516.163; information to be contained in a request to FDA to transfer ownership of a drug's index file to another person	1	1	1	2	2
516.165; requires drug experience reports and distributor statements to be submitted to FDA	10	10	100	5	500
Total					5,223

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
516.141, requires the qualified expert panel leader to maintain a copy of the written report and all notes or minutes relating to panel deliberations that are submitted to the requestor for 2 years after the report is submitted.	30	2	60	0.5 (30 minutes)	30
516.165, requires the holder of an indexed drug to maintain records of all information pertinent to the safety or effectiveness of the indexed drug, from foreign and domestic sources.	10	2	20	1	20
Total					50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We based our estimates in tables 1 and 2 on our experience with the MUMS indexing program and the requests for eligibility for indexing and for addition to the index, as well as the periodic drug experience reports submitted during the past 3 years.

Our estimated burden for the information collection reflects an overall increase of 351 reporting hours and a corresponding increase of 85 responses. We attribute this adjustment, generally, to an increase in the number of submissions we received over the last few years. We also reduced our burden hour estimate for drug experience reports and distributor statements under § 516.165 from 8 hours per submission to 5 hours per submission based on our experience with this type of reporting.

Dated: April 23, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–09170 Filed 4–29–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

Ophthalmic Devices Panel of the Medical Devices Advisory Committee: Notice of Meeting; Postponement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; postponement.

SUMMARY: The Food and Drug Administration (FDA) is postponing the

meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee scheduled for June 9, 2020. The meeting was announced in the **Federal Register** of April 1, 2020. FDA, like other government agencies, is taking the necessary steps to ensure the Agency is prepared to continue our vital public health mission in the event that our day-to-day operations are impacted by the COVID–19 public health emergency. Therefore, we are postponing this meeting and will reassess on an ongoing basis for future months. A future meeting date will be announced in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, *Aden.Asefa@fda.hhs.gov,* 301–796–0400, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: The meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee was originally announced in the **Federal Register** of April 1, 2020 (85 FR 18249), and was initially scheduled for June 9, 2020. FDA continues to evaluate whether and how to proceed with upcoming scheduled meetings while our day-to-day operations are impacted by the COVID–19 public health emergency, and we have decided to postpone this public meeting until further notice.

Dated: April 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–09232 Filed 4–29–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0424]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Safety Information Sharing by Constituent Part Applicants for Combination Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirements under the Postmarketing Safety Reporting Rule for Combination Product for Constituent Part Applicants to share specified adverse event information with one another.

DATES: Submit either electronic or written comments on the collection of information by June 29, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 29, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 29, 2020. 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–2008–N–0424 for ''Postmarketing Safety Information Sharing by Constituent Part Applicants for Combination Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*