TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section [Form Number]	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Hours Per Response	Total Hours
314.50(i) and 314.94(a)(12)	96	9.61	923	2	1,846
314.50(j)	71	4.02	286	2	572
314.52 and 314.95	71	3.66	260	16	4,160
314.60	305	15.05	4,590	80	367,200
314.65	13	1.08	14	2	28
314.70 and 314.71	281	9.30	2,613	150	391,950
314.72	69	3.40	235	2	470
314.81(b)(1) [3331]	114	2.68	306	8	2,448
314.81(b)(2) [2252]	724	11.15	8,073	40	322,920
314.81(b)(3)(i) [2253]	390	61.39	23,942	2	47,884
314.94(a)(1)-(11) and (d)	110	7.21	793	480	380,640
314.96	300	28	8,400	80	672,000
314.97	215	20.66	4,442	80	355,360
314.99(a)	40	2.02	81	2	162
314.101(a)	1	1	1	.50	.50
314.107(c) - 314.107(e) - 314.107(f) -	56 25 56	4.1 3.92 4.1	230 98 230	.50 .50 .50	115 49 115
314.110(a)(5)	45	1.15	52	.50	26
314.120(a)(5)	10	1.20	12	.50	6
314.420	487	1.98	964	61	58,804
Total					2,836,795.5

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

Dated: April 10, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–8459 Filed 4–17–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0224]

Draft Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff: Certifications to Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance With Section 402(j) of the Public Health Service Act, Added by Title VIII of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or agency) is announcing the availability of a draft guidance for industry entitled ''Guidance for Sponsors, Industry, Researchers, Investigators, and FDA Staff: Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act (PHS Act), Added By Title VIII of The Food and Drug Administration Amendments Act of 2007.'' The draft guidance provides sponsors, industry, researchers, investigators, and FDA staff with the agency's views on some types of information and documents submitted to FDA that typically need not be accompanied by the certification described in section 402(j)(5)(B) of the PHS Act.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the

final version of the guidance, submit written or electronic comments on the draft guidance by June 17, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Policy (HF–11), Office of Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85) amended the PHS Act by adding new section 402(j) (42 U.S.C. 282(j)). The new provisions require that additional information be submitted to the clinical trials data bank (*www.ClinicalTrials.gov*) previously established by the National Institutes of Health (NIH)/National Library of Medicine, including expanded information on clinical trials and information regarding the results of clinical trials.

One new provision, section 402(j)(5)(B) of the PHS Act, requires that a certification accompany certain human drug, biological product, and device applications and submissions to FDA. The purpose of title VIII of FDAAA is to provide a means for ensuring that the public has access to information about certain clinical trials. Specifically, title VIII is intended to provide a mechanism for the public to learn about clinical trials that are being conducted, as well as the results of those trials. The certification, which accompanies certain applications and submissions to FDA, plays a role in helping to achieve the purposes of title VIII of FDAAA. One purpose of the certification is to require the submitter to confirm that it has complied with all applicable requirements of title VIII, including the requirement to register applicable clinical trials. Failure to submit a certification, knowingly submitting a false certification, failure to submit required clinical trial information, and submission of clinical trial information that is false or misleading are all newly added prohibited acts under section 301(jj) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 331(jj)). Requiring a certification to accompany certain information and documents submitted to FDA is, therefore, one way of encouraging compliance with the provisions of the law.

The certification also serves the purpose of enabling FDA to exercise its responsibilities under the new law. The certification is critical to the agency's ability to determine whether the law has been complied with and whether a party has committed any of the new prohibited acts under section 301(jj) of the FD&C Act such that an enforcement action is appropriate. Section 402(j)(3)(F) of the PHS Act also requires FDA to notify the Director of NIH of certain actions taken on applications and reports that were accompanied by a certification. That notification alerts NIH to the fact that the responsible party must submit the results of the trials within a certain period of time, thereby enabling NIH to exercise its responsibilities under title VIII of FDAAA. The information in the certification form also will help FDA assist NIH in ''linking'' information posted on FDA's Web site regarding certain FDA regulatory actions to specific applicable clinical trials included in ClinicalTrials.gov. This linking, using the information in the certification form, eventually will allow FDA to help the public more easily correlate various reports, medical reviews, advisories, health alerts, advisory committee actions, and other materials with specific applicable clinical trials registered with ClinicalTrials.gov.

The certification requirement went into effect on December 26, 2007. To assist sponsors, industry, researchers, and investigators in complying with the requirement, FDA created a certification form, FDA Form 3674, that they may use to satisfy the certification requirement. Since the provision went into effect, FDA has received numerous inquiries asking whether various kinds of information and documents that sponsors, industry, researchers, and investigators submit to the agency should be accompanied by the certification.

The purpose of this draft guidance document is to provide FDA's current thinking regarding specific types of information and documents submitted to FDA under section 505, 515, 520(m), or 510(k) of the FD&C Act (21 U.S.C. 355, 360e, 360j(m), or 360(k)), or under section 351 of the PHS Act (42 U.S.C. 262) that typically need not be accompanied by the certification described in section 402(j)(5)(B) of the PHS Act. In determining whether specific information or documents submitted under the previously noted statutory sections typically should be accompanied by a certification, FDA has focused on the role the certification plays in achieving the purposes of title VIII of FDAAA. We believe that it would not further the purposes of the legislation if a certification were to accompany every type of information or document submitted to the agency regarding a medical product regulated by FDA.

While we intend the draft guidance to assist submitters in determining whether to submit a certification based on the type of document being submitted to FDA, this guidance does not address, nor does it make a recommendation on, all possible information and documents that may be submitted to FDA under those sections of the FD&C Act or the PHS Act. The guidance is currently limited to those specific types of submissions of information or documents described in the draft guidance. We will continue to review the types of information and documents that a certification typically does not need to accompany. We are interested in receiving comments from sponsors, industry, researchers, and investigators about additional types of information and documents submitted to FDA that typically need not be accompanied by a certification. (See section II of this document for instructions on how to submit comments on the draft guidance.) We intend to update this draft guidance document as appropriate to address additional information and documents that may be submitted under those sections and whether a certification should accompany those types of submissions of information or documents.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on those types of submissions of information or documents a certification typically does not need to accompany. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations.

II. Comments

We are interested in receiving comments from sponsors, industry, researchers, investigators, and other interested stakeholders on other types of information and documents that typically need not be accompanied by a certification. A description of the specific type of information or document and an explanation of the rationale for why a certification should not be necessary will assist us in evaluating the need for an accompanying certification.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved under OMB control no. 0910–0616.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at either *http://www.fda.gov/oc/initiatives/advance/fdaaa.html* or *http://www.regulations.gov*.

Dated: April 14, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–8349 Filed 4–17–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 29, 2008, from 8 a.m. to 1 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, Rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, Rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Yvette.Waples@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512534. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 22–212, difluprednate ophthalmic emulsion, Sirion Therapeutics, Inc., proposed for the treatment of inflammation and pain following ocular surgery.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 14, 2008. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 6, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 7, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Yvette Waples at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 10, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–8351 Filed 4–17–08; 8:45 am]

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