Therefore, the estimated annual reporting burden for this information collection is 33 hours.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: January 12, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–937 Filed 1–16–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0224]

Final 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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or agency) is announcing the availability of a guidance for industry entitled ''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'' dated January 2009. The guidance provides sponsors, industry, researchers, investigators, and FDA staff with the agency's current thinking regarding the types of applications and submissions that sponsors, industry, researchers, and investigators submit to FDA and accompanying certifications as described in Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy, Office of Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4305, Silver Spring, MD 20993–0002, 301–796–4830. Send one self addressed adhesive label to assist that office in processing your requests. 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy, Office of Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4305, Silver Spring, MD 20993–0002, 301–796–4830.

SUPPLEMENTARY INFORMATION:

I. Background

Title VIII of FDAAA, Public Law 110–85, amended the Public Health Service (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 (NLM), including expanded information on clinical trials and information regarding the results of clinical trials.

The purpose of Title VIII 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. One provision of Title VIII (section 401(j)(5)(B) of the PHS Act, 42 U.S.C. 282(j)(5)(B)) requires that a certification accompany certain human drug, biological product, and device applications and submissions to FDA.

The certification required under section 402(j)(5)(B) of the PHS Act (42 U.S.C. 282(j)(5)(B)) 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. ''Applicable clinical trial'' is defined at section 402(j)(1)(A)(i) of the PHS Act (42 U.S.C. 282(j)(1)(A)(i)). For additional information on this definition and other relevant definitions, visit the NIH Web site at *http://prsinfo.clinicaltrials.gov*.

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, as added by Title VIII of FDAAA, prohibited acts under section 301(jj) of the Federal Food, Drug, and Cosmetic Act (the act). Requiring a certification to accompany certain applications and submissions submitted to FDA is, therefore, one way of encouraging compliance with the provisions of the law.

The certification also facilitates FDA's exercise of its responsibilities under the law. The certification requirement is critical to the agency's ability to determine whether the law has been complied with and whether an enforcement action is appropriate under any of the prohibited acts under section 301(jj) of the act. Additionally, section 402(j)(3)(F) of the PHS Act (42 U.S.C. 282(j)(3)(F)) 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. The information provided 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 the registry and results databases. This linking, using the information in the certification form, particularly the NCT (National Clinical Trial) number(s) required in the 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 and identified by the NCT number.

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, OMB Control No. 0910–0616, to be used 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 must be accompanied by the certification. On April 18, 2008, FDA published a draft guidance on the certification requirement. In the draft guidance FDA provided a list of the types of submissions and applications that typically did *not* need to be accompanied by a certification. We received a number of comments to the docket concerning whether a certification should accompany the types of submissions and applications listed in the draft guidance, as well as other types of documents and information submitted to FDA. We also received a number of comments on this issue during the process for obtaining clearance under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) for the certification form itself. In addition, FDA also has had more experience with the submission of the certification form since the form was implemented.

The comments we received in response to the draft guidance and the development of the certification form, the inquiries to the agency, and our evolving experience caused us to reconsider our initial approach of identifying those documents and information that did not need to be accompanied by a certification. Instead, we concluded that it was more useful to identify those applications and submissions that must be accompanied by a certification. This approach is also consistent with many of the comments, which asked that we provide more specific information than was included in the draft guidance. Thus, we intend to exercise enforcement discretion concerning the submission of a certification with certain categories of applications and submissions to FDA, as noted in the guidance.

This guidance describes FDA's current thinking, for purposes of implementing Title VIII of FDAAA, regarding specific types of applications and submissions submitted to FDA under section 505, 515, 520(m), or 510(k) of the act, or under section 351 of the PHS Act, and accompanying certifications described in section 402(j)(5)(B) of the PHS Act, 42 U.S.C. 282(j)(5)(B). We note that the Agency's discussion of ''applications'' and ''submissions'' in this guidance is not necessarily applicable to any other provision of law. In determining how to interpret the certification requirement, FDA has focused on the plain language of Title VIII of FDAAA, as well as information that Title VIII is intended to capture.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking regarding the certification requirement in section 402(j)(5)(B) of the PHS Act (42 U.S.C. 282(j)(5)(B)). 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

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This guidance refers to a previously approved collection of information. This collection of information is 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 collection of information has been approved under OMB Control No. 0910–0616.

IV. Electronic Access

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

Dated: January 15, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–1183 Filed 1–15–09; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0018]

Report of Quantitative Risk and Benefit Assessment of Commercial Fish Consumption, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population, and Summary of Published Research on the Beneficial Effects of Fish Consumption and Omega-3 Fatty Acids for Certain Neurodevelopmental and Cardiovascular Endpoints; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft documents. The first is entitled ''Report of Quantitative Risk and Benefit Assessment of Commercial Fish Consumption, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population'' (draft risk and benefit assessment report). The draft risk and benefit assessment report describes an analysis done by FDA that results in quantitative estimates of the net effect on fetal neurodevelopment in children of maternal consumption of commercial fish, as measured by verbal development and the net effect of eating commercial fish on coronary heart disease and stroke in the general population. Effects with respect to each of these health endpoints has been associated in the scientific literature with methylmercury exposure (which primarily occurs through fish consumption) and with the consumption of fish and of omega-3 fatty acids, which are found in fish. The second draft document entitled ''Summary of Published Research on the Beneficial Effects of Fish Consumption and Omega-3 Fatty Acids for Certain Neurodevelopmental and Cardiovascular Endpoints'' (draft summary of published research) is a compendium of research prepared by FDA for use in developing its quantitative risk and benefit assessment. When peer and public review are complete, the draft risk and benefit assessment report and the draft summary of published research are intended to add to the growing body of scientific literature investigating the