TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR WATER SOLUBLE POWDERS[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Same formulation/manufacturing process approach	1	1	1	5	5
Same API/solubility approach	5	5	5	10	50
Total burden hours					55

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES[1]

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Same formulation/manufacturing process approach	2	2	2	5	10
Same API/solubility approach	10	10	10	20	200
Total burden hours					210

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

The sources of the previous data are records of generic drug applications over the past 10 years.

Dated: January 8, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–782 Filed 1–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0202] (formerly Docket No. 2007D–0106)

Guidance for Clinical Investigators, Sponsors, and Institutional Review Boards on Adverse Event Reporting—Improving Human Subject Protection; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Adverse Event Reporting—Improving Human Subject Protection.'' This guidance is intended to assist the research community in interpreting requirements for submitting reports of unanticipated problems, including certain adverse events reports, to institutional review boards (IRBs). FDA developed this guidance in response to concerns raised by the IRB community that increasingly large volumes of individual, unanalyzed adverse event reports are inhibiting, rather than enhancing, the ability of IRBs to adequately protect human subjects. The guidance provides recommendations to IRBs, sponsors, and investigators on improving the usefulness of the adverse event information submitted to IRBs. Elsewhere in this issue of the **Federal Register**, FDA is issuing the final rule entitled ''Institutional Review Boards; Registration Requirements.''

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

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance 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: Joseph Griffin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2270, e-mail: *Joseph.Griffin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for clinical investigators, sponsors, and IRBs entitled ''Adverse Event Reporting—Improving Human Subject Protection.'' Under the regulations in 21 CFR part 50 (Protection of Human Subjects), part 56 (21 CFR part 56) (Institutional Review Boards), part 312 (21 CFR part 312) (Investigational New Drug Application), and part 812 (21 CFR part 812) (Investigational Device Exemptions), an IRB must review and approve a clinical study before the study is initiated. Additionally, after an IRB's initial review and approval, an IRB must conduct continuing review of the study at intervals appropriate to the degree of risk presented by the study, at least annually. The primary purpose of both the initial review of a study and the periodic review of the conduct of the study is to ensure the protection of the rights and welfare of human subjects. To do its job, an IRB must be informed of any unanticipated problems in the study and any changes in the research activity. This guidance discusses adverse event reporting to IRBs by sponsors and investigators and emphasizes the value of well-analyzed adverse event data to an IRB review.

A notice announcing the draft version of this guidance published in the **Federal Register** on April 9, 2007 (72 FR 17562). After carefully considering all received comments, the agency is finalizing that guidance. The draft and the final have relatively minor substantive differences. The recommendations section in the final

guidance is streamlined and re-organized to make the information clearer and more accessible, but there are no major policy differences. The final guidance also omits much of the background discussion about the origin and nature of the adverse event reporting problem that the guidance addresses because that information is tangential to the goals of the guidance.

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 on adverse event reporting for the purpose of improving human subject protection. 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 the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This 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 in part 56 have been approved under OMB control number 0910–0130; the collections of information in part 312 have been approved under OMB control number 0910–0014; and the collections of information in part 812 have been approved under OMB control number 0910–0078.

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 only through FDMS at *http://www.regulations.gov*.

Dated: December 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–683 Filed 1–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0043] (formerly Docket No. 2004D–0510)

Guidance for Industry: Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association.'' The guidance provides information for seafood processors and other entities that are interested in obtaining export certificates for fish or fishery products that are to be shipped to the European Union (EU) and the European Free Trade Association (EFTA). FDA is also announcing that it intends to stop issuing EU Export Certificates after February 17, 2009.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written comments concerning the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written requests for single copies of the guidance to the Office of Food Safety (HFS–300), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: William Jones, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2300.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 26, 2004 (69 FR 68948) (the November 26 notice), FDA announced the availability of a draft guidance entitled ''Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association.'' In the November 26 notice, FDA announced that it proposed to operate a Referral Program for a 24-month period to test the viability and effectiveness of such an arrangement. During this period, EU Export Certificates for shipments of live and perishable fish and fishery products destined for the EU, European Union Accession Partnership Countries (EUAPC), and EFTA Members would have been issued by the National Oceanic and Atmospheric Administration Seafood Inspection Program (NOAA SIP) under the Agricultural Marketing Act. In addition, FDA indicated that it intended to stop issuing EU Export Certificates for live and perishable fish and fishery products during this period. FDA sought comment on this referral program, including whether it should be expanded beyond live and perishable to all shipments of fish and fishery products destined for the EU, EU Accession Partnership Countries, and other countries with certificate requirements.

Interested persons were initially given until December 27, 2004, to comment on the draft guidance. The comment period was subsequently extended until January 25, 2005 (69 FR 78038, December 29, 2004). The agency considered and modified the guidance as appropriate.

The agency is announcing the availability of the final guidance document entitled ''Guidance for Industry: Referral Program from the Food and Drug Administration to the National Oceanic and Atmosphere Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for the Export to the European Union and the European Free