before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Currently, FDA's Center for Drug Evaluation and Research, Division of Scientific Investigations (DSI), receives an average of about 150 unsolicited complaints per year about scientific misconduct in clinical research through electronic mail, regular mail, telephone, and personal contacts. DSI will continue to receive and process such complaints. The internet-based complaint form for consumer complaints on research studies will provide an additional convenient and efficient way for the public to submit complaints regarding misconduct in clinical research. The complaint form asks questions about the individual, company, or organization that is the subject of the complaint; the event and the drug product(s) that prompted the complaint; and optional information about the person submitting the complaint. The complaint form is accessible at *http://didit.devis.com/complaints*. The username is ''public'' and the password is ''fdapublic.''

FDA will use the information collected through the complaint form to identify weaknesses in the current services provided to human subjects in clinical research and to improve and maintain a high quality of service to the affected public. The complaint form will be encrypted so that any information of a sensitive nature will not be unnecessarily or prematurely disclosed. The complainants will remain anonymous unless they voluntarily disclose their identity. Participation is fully voluntary and complainants will be able to complete, review, edit, and submit the form to FDA. DSI will acknowledge the receipt of each complaint.

DSI will complete initial analyses of the information from each complaint within 10 working days. Each complaint will be reviewed by a responsible person in DSI and then distributed to the appropriate unit in DSI or FDA for further action. DSI will contact the complainant if the complainant requests a followup contact. If the complainant does not request any followup contact, then no additional contact with the complainant is anticipated.

FDA estimates that approximately 144 persons will voluntarily complete the complaint form each year. The estimated time for completing each complaint form will be 1 hour, resulting in a total burden of 144 hours per year (144 complainants x 1 hour = 144 burden hours per year). The burden of this collection of information is estimated as follows:

TABLE 1.—ESTIMATED ONE-TIME REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Hours
144	1	144	1	144

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

Dated: June 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16494 Filed 6–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0268]

Agency Information Collection Activities; Proposed Collection; Comment Request; Biological Products: Reporting of Biological Product Deviations in Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the 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 information collection requirements relating to the reporting of biological product deviations in manufacturing.

DATES: Submit written or electronic comments on the collection of information by August 29, 2003.

ADDRESSES: 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.fda.gov/dockets/ecomments*. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520) Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed

collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Biological Products: Reporting of Biological Product Deviations in Manufacturing (OMB Control Number 0910–0458)—Extension

Under section 351 of the Public Health Service Act (42 U.S.C. 262), all biological products, including human blood and blood components, offered for sale in interstate commerce must be licensed and meet standards designed to ensure the continued safety, purity, and potency of such products. In addition, the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351) provides that drugs and devices (including human blood and blood components) are adulterated if they do not conform with Current Good Manufacturing Practice (CGMP) assuring that they meet the requirements of the act. All establishments manufacturing human blood and blood components are required to register with FDA, and comply with the CGMP regulations for human blood and blood components (parts 211 and 606 (21 CFR parts 211 and 606)). Transfusion services are required under 42 CFR 493.1273(a) to comply with part 606 and 21 CFR 640 as they pertain to the performance of manufacturing activities. FDA regards biological product deviation reporting to be an essential tool in its directive to protect public health by establishing and maintaining surveillance programs that provide timely and useful information.

Section 600.14 (21 CFR 600.14) requires the licensed manufacturer who holds the biological product license, for other than human blood and blood components, and who had control over the product when the deviation occurred, to report to the Center for Biologics Evaluation and Research (CBER) as soon as possible but not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Section 606.171 requires a licensed manufacturer of human blood and blood components, including Source Plasma; an unlicensed registered blood establishment; or a transfusion service who had control over the product when the deviation occurred, to report to CBER as soon as possible but not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred.

Respondents to this collection of information are the licensed manufacturers of biological products other than human blood and blood components, unlicensed registered blood establishments, and transfusion services. Based on information from CBER's databases for fiscal year (FY) 2002, the agency estimates that 115 licensed manufacturers of biological products other than human blood and blood components submitted 476 error and accident reports under § 600.14. FDA also estimates 207 licensed manufacturers of human blood and blood components, including Source Plasma, submitted 27,000 error and accident reports under § 606.171. In addition, FDA estimates 2,800 unlicensed registered blood establishments and 3,221 transfusion services submitted a total of 6,446 error and accident reports. The number of total annual responses is based on the number of biological product deviation reports CBER received in FY 2002. The rate of submission is not expected to change significantly in the next few years. Based on information from industry, the estimated average time to complete a deviation report is 2 hours. The availability of the standardized report FDA Form 3486, and the ability to submit this report electronically further streamlines the report submission process. Activities such as investigating, changing SOP's or processes, and follow-up are currently required under parts 211 (approved under OMB control numbers 0910–0139 and 0910–0353), 606 (approved under OMB control number 0910–0116), and 21 CFR part 820 (approved under OMB control number 0910–0073) and, therefore, are not included in the burden calculation for the separate requirement of submitting a deviation report to FDA.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
600.14	3486	115	4.1	476	2	952
606.171[2]	3486	207	130.4	27,000	2	54,000
606.171[3]	3486	6,021	1.1	6,446	2	12,892
Total	3486	6,343		33,922		67,844

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Licensed manufacturers of human blood and blood components, including Source Plasma.
[3] Unlicensed registered blood establishments and transfusion services (2,800+3,221=6,021).

Dated: June 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16495 Filed 6–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management 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: Drug Safety and Risk Management Advisory Committee.

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