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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier J COOKE

[Docket No. 2003N-0273]

Agency Information Collection Activities; Proposed Collection; Comment Request; Research Study Complaint Form

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's burden estimates to use an Internet-based complaint form for public complaints concerning misconduct in research studies.

**DATES:** Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.



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**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**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 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<sup>1</sup>

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

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: 6/24/03  
June 24, 2003.

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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