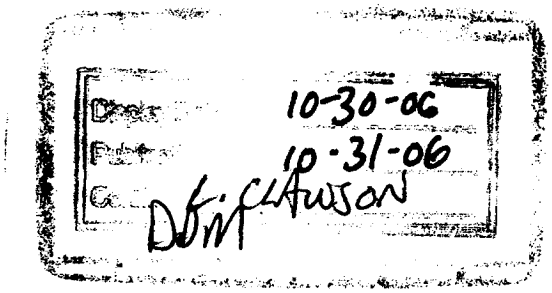
DEPARTMENT OF HEALTH AND HUMAN SERVICES



Food and Drug Administration

[Docket No. 2006N–0421]

Agency Information Collection Activities; Proposed Collection; Comment Request; Biological Products: Reporting of Biological Product Deviations in Manufacturing; Forms FDA 3486 and 3486A

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, and Forms FDA 3486 and 3486A.

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

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20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (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 these topics: (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; Forms FDA 3486 and 3486A (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 biological products including human blood and blood components must comply with the applicable CGMP regulations (parts 211, 606, and 820 (21 CFR parts 211, 606, and 820)). Transfusion services are required under 42 CFR 493.1271 to comply with 21 CFR parts 606 and 640 as they pertain to the performance of manufacturing activities. FDA regards biological product deviation (BPD) 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 requires the 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) or to the Center for Drugs Evaluation and Research (CDER) 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. The BPD reporting under 21 CFR 1271.350(b) for human cells, tissues, and cellular and tissue-based products is approved under OMB control number 0910–0559 (expires November 30, 2007). Form FDA 3486 is used to submit BPDs under these regulations.

Respondents to this collection of information are the licensed manufacturers of biological products other than human blood and blood components, licensed manufacturers of blood and blood components including Source Plasma, unlicensed registered blood establishments, and transfusion services. Based on information from FDA's database, there are an estimated 147 licensed manufacturers of biological products other than human blood and blood components, 194 licensed manufacturers of human blood and blood components, including Source Plasma, and 1,230 unlicensed registered blood establishments. Based on the Center for Medicare and Medicaid Services records, there are an estimated 4,980 transfusion services. The number of licensed manufacturers and total annual responses under § 600.14 include the estimates for both CBER and CDER. The number of total annual responses is based on the number of BPD reports FDA received in fiscal year 2005. 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 form,

Form FDA 3486, and the ability to submit this report electronically to CBER (CDER does not currently accept electronic filings) further streamlines the report submission process.

CBER is developing an addendum to Form FDA 3486. The web-based addendum (Form FDA 3486A) would request additional information when a BPD report has been reviewed by FDA and evaluated as a possible recall. The additional information requested would include information not contained in the Form FDA 3486 such as: (1) Distribution pattern, (2) method of consignee notification, (3) consignee(s) of products for further manufacture, (4) additional product information, and (5) updated product disposition. This information would be requested by CBER through e-mail notification to the submitter of the BPD report. This information would be used by CBER for purposes of recall classification. We plan to use Form FDA 3486A for only biological products regulated by CBER. We do not plan to use this form for biological products regulated by CDER because they receive very few BPD reports and do not accept electronic filings. CBER estimates that 5 percent of the total BPD reports submitted to CBER would need additional information submitted in the addendum. CBER estimates it would take between 15 to 45 minutes to complete the addendum. For calculation purposes, CBER is using one-half hour.

Activities such as investigating, changing standard operating procedures or processes, and followup are currently required under 21 CFR parts 211 (approved under OMB control no. 0910–0139, expires September 30, 2008), 606 (approved under OMB control no. 0910–0116, expires December 31, 2008), and 820 (approved under OMB control no. 0910–0073, expires September 30,

2007) and, therefore, are not included in the burden calculation for the separate requirement of submitting a BPD report to FDA.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Responses	Total Hours
600.14	3486	147	2.73	401	2.0	802
606.171[2]	3486	194	169.89	32,958	2.0	65,916
606.171[3]	3486	6,210	1.50	9,311	2.0	18,622
	3486A[4]	6,551	0.33	2,133	0.5	1,067
Total						86,407

[1] There are no capital costs or 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 (1,230 + 4,980 = 6,210).
[4] Five percent of the total annual responses to CBER (42,653 x 0.05 = 2,133).

Dated: 10/25/06
October 25, 2006.

oc06244

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

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