Dated: November 12, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0545]

Agency Information Collection Activities; Proposed Collection; Comment Request; Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing; Form FDA 3486 and Addendum 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 (BPDs) and human cells, tissues, and cellular and tissue-based product (HCT/P) deviations, and Form FDA 3486 and Addendum 3486A.

DATES: Submit written or electronic comments on the collection of information by January 19, 2010.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.regulations.gov*. 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.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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 and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations; Form FDA 3486 and Addendum 3486A (OMB Control Number 0910–0458)—Extension

Under section 351 of the Public Health Service Act (PHS 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, including those prescribed in the FDA regulations, designed to ensure the continued safety, purity, and potency of such products. In addition under section 361 of the PHS Act (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign countries into the States or possessions. Further, 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. 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)) and current good tissue practice (CGTP) regulations (part 1271 (21 CFR part 1271)) as appropriate. FDA regards BPD reporting and HCT/P 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, in brief, requires the manufacturer who holds the biological product license, for other than human blood and blood components, and who had control over a distributed 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, in brief, 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 a distributed 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. Similarly § 1271.350(b), in brief, requires non-reproductive HCT/P establishments described in § 1271.10 to report to CBER all HCT/P deviations relating to a distributed HCT/P that relates to the core CGTP requirements, if the deviation occurred in the establishment's facility or in a facility that performed a manufacturing step for the establishment under contract, agreement or other arrangement. Form FDA 3486 is used to submit BPD reports and HCT/P deviation reports.

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, transfusion services, and establishments that manufacture non-reproductive HCT/Ps

regulated solely under section 361 of the PHS Act as described in § 1271.10. The number of respondents and total annual responses are based on the BPD reports and HCT/P deviation reports FDA received in fiscal year (FY) 2008. The number of licensed manufacturers and total annual responses under 21 CFR 600.14 include the estimates for BPD reports submitted to both CBER and CDER. Based on the 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 has developed an addendum to Form FDA 3486. The web-based addendum 3486A provides additional information when a BPD report has been reviewed by FDA and evaluated as a possible recall. The additional information requested includes 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, (5) updated product disposition, and (6) industry recall contacts. This information is requested by CBER through e-mail notification to the submitter of the BPD report. This information is used by CBER for recall classification purposes. At this time Addendum 3486A is being used only for those BPD reports submitted under § 606.171. CBER estimates that 5 percent of the total BPD reports submitted to CBER under § 606.171 would need additional information submitted in the addendum. CBER further estimates that it would take between 10 to 20 minutes to complete the addendum. For calculation purposes, CBER is using 15 minutes.

Activities such as investigating, changing standard operating procedures or processes, and follow-up are currently required under 21 CFR parts 211, (approved under OMB control number 0910–0139), part 606 (approved under OMB control number 0910–0116), part 820 (approved under OMB control number 0910–0073), and part 1271 are approved under OMB Control No. 0910–0543 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	51	7.78	397	2.0	794
606.171	3486	1,533	28.78	44,125	2.0	88,250
1271.350(b)	3486	84	2.64	222	2.0	444
	3486A[2]	77	28.65	2,206	0.25	551.5
Total						90,039.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Five percent of the number of respondents (1,533 x 0.05 = 77) and total annual responses to CBER (44,125 x 0.05 = 2,206).

Dated: November 12, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; Comment Request; Parental Knowledge, Attitudes, and Behaviors Related to Pediatric Cardiovascular Health

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on Wednesday, July 29, 2009, Volume 74, Number 144 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

5 CFR 1320.5 (General requirements) Reporting and Recordkeeping Requirements:

Final Rule requires that the agency inform the potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. This information is required to be stated in the 30-day **Federal Register** Notice.

Proposed Collection: Describe the proposed information collection activity as follows. Include: *Title:* Parental Knowledge, Attitudes, and Behaviors Related to Pediatric Cardiovascular Health; *Type of Information Collection Request:* New; *Need and Use of Information Collection:* Coinciding with the release of the Integrated Pediatric Cardiovascular Risk Reduction Guidelines, the National Heart, Lung, and Blood Institute (NHLBI) will conduct a national public awareness campaign to help parents understand that risk for cardiovascular disease (CVD) begins in childhood, and to engage them in encouraging healthy habits in their children to promote heart health and reduce their children's CVD risk now and as they grow. Currently, little is known about parental knowledge, attitudes, and behaviors related to heart health in children. Serving as a baseline for evaluation of NHLBI's outreach activities related to the campaign, this study seeks to learn the following: (a) Parents' awareness of cardiovascular disease risk factors in children and knowledge of what to do for risk reduction, (b) parents' level of efficacy toward taking action to promote cardiovascular health and reduce risk factors, and (c) parents' behaviors related to cardiovascular health. The findings will provide valuable information that will enable NHLBI to identify the gaps in knowledge and awareness and target specific