

analyzes and disseminates program data from the Adoption and Foster Care Analysis and Reporting System (AFCARS), and the National Child Abuse and Neglect Data System (NCANDS); develops systematic methods of measuring the impact and effectiveness of various child welfare programs; performs statistical sampling functions; provides comprehensive guidance to States, local agencies and others on data collection issues, and performance outcome measures; and is the focal point for technology development within the Bureau.

C. Delete KB.20 Functions, Paragraph D.4, in its entirety and replace with the following:

4. The Division of Research and Innovation provides leadership and direction in program development, innovation, research and in the management of the Bureau's information systems under titles IV-B and IV-E of the Social Security Act, and under the Child Abuse Prevention and Treatment Act. It defines critical issues for investigation and makes recommendations regarding subject areas for research, demonstration and evaluation. It administers the Bureau's discretionary grant programs, and awards project grants to State and local agencies and organizations nationwide. It provides direction to the Crisis Nurseries and Abandoned Infants Resource Centers.

Dated: December 9, 2003.

Wade F. Horn,

Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0268]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 30, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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, section 501 of 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 part 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, there were 115 licensed manufacturers of biological products other than human blood and blood components, 207 licensed manufacturers of human blood and blood components, including Source Plasma, and 2,800 unlicensed registered blood establishments and 3,221 transfusion services. However, not all manufacturers or establishments may have any submissions in a given year and some may have multiple submissions. In the same FY, CBER's database also showed that the licensed manufacturers of biological products other than human blood and blood components submitted 476 biological product deviation reports (BPDRs) under § 600.14, the licensed manufacturers of human blood and blood components, including Source Plasma submitted 27,000 BPDRs under § 606.171, and the unlicensed registered blood establishments and transfusion services submitted a total of 6,446 BPDRs. The number of total annual responses is based on the number of BPDRs 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 standard operating procedures (SOPs) or processes, and followup are currently required under parts 211 (approved under OMB control numbers 0910-0139