ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Estimated Total Annual Burden Hours				8,200

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: November 25, 2002.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 02–30645 Filed 12–2–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administrative for Children and Families

Submission for OMB Review; Comment Request

Title: 45 CFR 1302 Head Start Grants Administration.

OMB No.: 0980–0243.

Description: 45 CFR contains provisions applicable to program administration and grants administration under the Head Start Act, as amended. The provisions specify the requirements for grantee agencies for insurance, bonding, the submission of audits, matching of federal funds, accounting systems certifications and other provisions applicable to personnel administration.

Respondents: Head Start and Early Start grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR Part 1301	2500	2	2	5,000

Estimated Total Annual Burden Hours: 5,000.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: November 25, 2002.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 02–30646 Filed 12–2–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0116]

Agency Information Collection Activities; Announcement of OMB Approval; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Veterinary Feed Directive 21 CFR Part 558,'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 19, 2002 (67 FR 53806), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0363. The approval expires on October 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: November 26, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–30643 Filed 12–2–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0476]

Bavarian Red Cross; Revocation of U.S. License No. 1002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the biologics license (U.S. License No. 1002), issued to the Bavarian Red Cross (BRC), for the manufacture of Whole Blood and Red Blood Cells. In a letter to FDA dated June 3, 2002, BRC voluntarily requested revocation of its licenses without prejudice and thereby waived its opportunity for a hearing. In a letter dated July 22, 2002, FDA revoked the firm's license.

DATES: The revocation of the biologics license (U.S. License No. 1002) is effective July 22, 2002.

FOR FURTHER INFORMATION CONTACT: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA has revoked the biologics license (U.S. License No. 1002), issued to BRC, Herzog-Heinrich-Strasse 4, D–80336, Munich, Germany, for the manufacture of Whole Blood and Red Blood Cells. Additional locations affected by the revocation include: Prof.-Ernst-Nathan-Str. 1, D–90419, Nurnburg, Germany; Klinikstrasse 5, D–97070, Wurzburg, Germany; Dr. Franz-Strasse 3, D–95445, Bayreuth, Germany; Westheimer Strasse 80, D–86156, Augsburg, Germany; Nikolaus-Fey-Strasse 32, D–97353, Wiesentheid, Germany; and Hoher Kreuz Weg 7, D–93055, Regensburg, Germany.

FDA inspected four of the six licensed locations of the BRC from October 27 through November 13, 1997. The inspections were conducted at the Munich, Wiesentheid, Nurnberg, and Bayreuth facilities. During the inspections, FDA observed significant deviations from the standards established in the license as well as the applicable Federal regulations. The standards and regulations are designed to ensure the continued safety, purity, and potency of the manufactured product. FDA also determined that the firm had discontinued the manufacture of Whole Blood and Red Blood Cells intended for distribution in the United States. FDA concluded that a meaningful inspection of BRC's ability to appropriately manufacture products under the license could not be made. The deviations noted during the inspections included, but were not limited to, the following: (1) In violation of 21 CFR 640.3(b), donor suitability was not adequately determined, in that questions were not asked, concurrently with the direct questions on high risk behavior, for exclusion of donors who are at increased risk for human immunodeficiency virus–1 (HIV–1) group O infection; (2) in violation of §§ 606.140, 610.40, and 610.45 (21 CFR 606.140, 610.40, and 610.45), inspections of the Nurnburg and Munich facilities disclosed that the Abbott Prism system, a device that was not approved by FDA, was utilized to test for antibody to HIV types 1 and 2 plus O (anti-HIV 1/2), the hepatitis B surface antigen (HBsAg), the antibody to hepatitis B core antigen (anti-HBc), and antibody to hepatitis C virus encoded antigen (anti-HCV). Additionally, blood and blood products were not tested for HIV–1 antigen and antibody to human lymphotropic virus type I (anti-HTLV–I); (3) in violation of § 606.140, the New LAV-Bolt I by Sanofi Diagnostics Pasteur, an HIV–1 western blot assay that was not approved by FDA, was used as an assay for reentry of donors; (4) in violation of § 606.140, the New LAV-Bolt II by Sanofi Diagnostics Pasteur, an HIV–2 western blot assay that was not approved by FDA, was used as an assay for reentry of donors; and (5) in violation of 21 CFR 606.121(c)(5)(i), blood and blood products that were intended for transfusion and collected from paid donors were not labeled as to distinguish them from blood products collected from volunteer donors.

In a letter dated July 8, 1998, and issued under § 601.5(b) (21 CFR 601.5(b)), FDA outlined the deviations noted at the inspection. FDA notified BRC of FDA's intent to revoke U.S. License No. 1002 and announced its intent to offer an opportunity for hearing unless the deviations were adequately addressed. In a letter to FDA dated July 30, 1998, BRC addressed FDA's concerns about the inability to inspect products prepared under the U.S. License No. 1002.

In a certified, return-receipt letter dated January 21, 1999, to BRC, FDA stated that the firm's July 30, 1998, response was inadequate to address all the violations that FDA documented at the inspections. FDA advised BRC that its response was unsatisfactory in that BRC had not provided a comprehensive corrective action plan, adequate to bring the firm into compliance with the applicable Federal standards and regulations. In the same letter, FDA suggested that the firm voluntarily request that U.S. License No. 1002 be revoked, and a new application be submitted at a later date.

In a letter dated November 3, 2000, FDA notified BRC that since the receipt of the July 30, 1998, letter to FDA, FDA had not received any additional response from the firm. The letter stated under § 601.5(b)(2), FDA had provided a reasonable period for the firm to demonstrate or achieve compliance with the applicable standards established in the license and regulations before proceeding to initiate revocation of U.S. License No. 1002. Since BRC did not submit a response addressing the methods intended to demonstrate or achieve compliance and did not waive an opportunity for hearing, FDA notified the firm in the same letter of FDA's intent to revoke the license and to issue a notice of opportunity for hearing under 21 CFR 12.21(b).

In the **Federal Register** of May 9, 2002 (67 FR 31348), FDA announced a notice of opportunity for a hearing on a proposal to revoke the biologics license (U.S. License No. 1002) issued to BRC. In a letter to FDA dated June 3, 2002, BRC voluntarily requested revocation of its licenses without prejudice and thereby waived its opportunity for a hearing. In a letter to BRC dated July 22, 2002, FDA revoked the firm's license.

FDA had placed copies of the documents relevant to the revocation on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this document.

Accordingly, under section 351 of the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, and 371), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of the Center for Biologics Evaluation and Research (21 CFR 5.202), the biologics license (U.S. License No. 1002) issued to BRC was revoked, effective July 22, 2002.