DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration on Developmental Disabilities 2004 Projects of National Significance; Notice of Corrections for the FY04 Projects of National Significance Program Announcement HHS–2004–ACF–ADD–DN–0003, CFDA# 93.631

AGENCY: Administration on Developmental Disabilities, ACF, DHHS.

ACTION: Notice of corrections.

SUMMARY: This notice is to inform interested parties of corrections to the Projects of National Significance Program Announcement that was published on Thursday, June 17, 2004 (69 FR 33905). The following corrections should be noted:

(1) Under Priority Areas I, II, and III, for 'Submission Dates and Times', Please Delete the following address for applications hand carried by applicants:

''U.S. Department of Health and Human Services, Administration for Children and Families, Office of Grants Management, 370 L'Enfant Promenade, SW., 8th Floor, Washington, DC 20447. Attention Lois Hodge.''

Please Replace this address with the following:

U.S. Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, ACF Mail Center, 2nd Floor Aerospace Center, 901 D Street, SW., Washington, DC 20024, Attention: Lois Hodge.

(2) Under Priority Areas I, II, and III, 'Other Submission Requirements' Please Delete the following address for hand delivered applications:

''U.S. Department of Health and Human Services, Administration for Children and Families, Office of Grants Management, 370 L'Enfant Promenade, SW., 8th Floor, Washington DC 20447. Attention Lois Hodge''.

Please Replace this address with the following:

U.S. Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, ACF Mail Center, 2nd Floor Aerospace Center, 901 D Street, SW., Washington, DC 20024, Attention: Lois Hodge.

(3) Under I. Funding Opportunity Description, 'Other General Information', 'Project Periods for Awards', Please Delete the following sentence:

''Three year project periods with twelve month budget periods.''

Please Replace this sentence with the following:

''The project period for Priority Area I is a five year project period with twelve month budget periods. The project period for Priority Area II is a one year project period of one twelve month budget period. The project period for Priority Area III is a three year project period with twelve month budget periods.''

(4) Under Priority Area I, 'Award Information', 'Project Periods for Awards' Please Delete the following sentence:

''This priority area is inviting applications for project periods up to three years.''

Please Replace with the following sentence:

''This priority area is inviting applications for project periods for up to five years.''

All information in this Notice of Correction is accurate and replaces information specified in the June 17 Notice. Applications are still due by the deadline date that was published in the June 17 Notice of August 2, 2004.

CONTACT INFO: For further information please contact The Administration on Developmental Disabilities at (202) 690–5985 or *amyers@acf.hhs.gov*.

Dated: July 1, 2004.

Patricia A. Morrissey,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 04–15676 Filed 7–9–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0101]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents; and Requirements for Donor Notification

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 August 11, 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: Jonna 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.

Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents; and Requirements for Donor Notification—(OMB Control Number 0910–0472)—Extension

Under sections 351 and 361 of the Public Health Service Act (PHS Act)(42 U.S.C. 262 and 264) and the provisions of the Federal Food, Drug, and Cosmetic Act (the act) that apply to drugs (21 U.S.C. 321 *et seq.*), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between States or Possessions or from foreign countries into the States or Possessions. The public health objective in testing human blood donors for evidence of infection due to communicable disease agents and in donor notification is to prevent the transmission of communicable disease. Section 351 of the PHS Act applies to biological products. Blood and blood components are considered drugs, as that term is defined in section 201(g)(1) of the act (21 U.S.C. 321(g)(1)).

Section 610.40(c)(1)(ii) (21 CFR 610.40(c)(1)(ii) requires each dedicated donation be labeled, as required under § 606.121 (21 CFR 606.121), and with a label entitled ''INTENDED RECIPIENT INFORMATION LABEL'' containing the name and identifying information of the recipient. (Section 606.121 is approved under OMB control number 0910–0116.) Section 610.40(g)(2) requires an

establishment to obtain written approval from FDA to ship human blood or blood components for further manufacturing use before completion of testing. Section 610.40(h)(2)(ii)(A) requires an establishment to obtain written approval from FDA to use or ship human blood or blood components found to be reactive by a screening test for evidence of a communicable disease agent(s) or collect from a donor with a record of a reactive screening test. Section 610.40(h)(2)(ii)(C) and (h)(2)(ii)(D) requires an establishment to label reactive human blood and blood components with the appropriate screening test results, and, if they are intended for further manufacturing use into injectable products, with a statement indicating the exempted use specifically approved by FDA. Section 610.40(h)(2)(vi) requires each donation of human blood or blood component that tests reactive by a screening test for syphilis and is determined to be a biological false positive be labeled with both test results. Section 610.42(a) requires a warning statement, including the identity of the communicable disease agent, on medical devices containing human blood or blood components found to be reactive by a screening test for evidence of infection due to a communicable disease agent(s) or syphilis. Section 630.6(a) (21 CFR 630.6(a)) requires an establishment to make reasonable attempts to notify any donor who has been deferred as required by § 610.41, or who has been determined not to be eligible as a donor. Section 630.6(d)(1) requires establishment to provide certain information to the referring physician of an autologous donor who is deferred based on the results of tests as described in § 610.41.

Section 610.40(g)(1) requires an establishment to appropriately document a medical emergency for the release of human blood or blood components prior to completion of required testing. Section 606.160(b)(1)(ix) requires a facility to maintain records of notification of donors deferred or determined not to be eligible for donation, including appropriate followup. Section 606.160(b)(1)(xi) requires an establishment to maintain records of notification of the referring physician of a deferred autologous donor, including appropriate followup.

Respondents to this collection of information are Whole Blood and Source Plasma establishments that collect blood and blood components, including Source Plasma and Source Leukocytes. Based on information from FDA's Center for Biologics and Evaluation Research (CBER) database system, there are approximately 84 licensed Source Plasma collection establishments and 858 registered Whole Blood collection establishments for a total of 942 establishments. Based on information received from industry, we estimate that these establishments collect annually an estimated 30 million donations: 15 million donations of Source Plasma from approximately 2 million donors and 15 million donations of Whole Blood, including 600,000 autologous, from approximately 8 million donors.

Assuming each autologous donor makes an average of two donations, FDA estimates that there are approximately 300,000 autologous donors. FDA estimates that approximately 5 percent (12,000) of the 240,000 donations that are donated specifically for the use of an identified recipient would be tested under the dedicated donors testing provisions in § 610.40(c)(1)(ii).

Under § 610.40(g)(2) and (h)(2)(ii)(A), the only product currently shipped prior to completion of testing is a licensed product, Source Leukocytes, used in the manufacture of interferon, which requires rapid preparation from blood. Shipments of Source Leukocytes are preapproved under a biologics license application and each shipment does not have to be reported to the agency. Based on information from CBER's database system, FDA receives an estimated one application per year from manufacturers of Source Leukocytes.

Under § 610.40(h)(2)(ii)(C) and (h)(2)(ii)(D), FDA estimates that each manufacturer would ship an estimated 1 human blood or blood components per month (12 per year) that would require 2 labels; 1 as reactive for the appropriate screening test under paragraph (h)(2)(ii)(C), and the other stating the exempted use specifically approved by FDA under paragraph (h)(2)(ii)(D). According to CBER's database system, there are an estimated 40 licensed manufacturers that ship known reactive human blood or blood components.

Based on information we received from industry, we estimate that approximately 18,000 donations annually test reactive by a screening test for syphilis, and are determined to be biological false positives by additional testing (§ 610.40(h)(2)(vi)).

Human blood or a blood component with a reactive screening test, as a component of a medical device, is an integral part of the medical device, e.g., a positive control for an in vitro diagnostic testing kit. It is usual and customary business practice for manufacturers to include on the container label a warning statement that identifies the communicable disease agent. In addition, on the rare occasion when a human blood or blood component with a reactive screening test is the only component available for a medical device that does not require a reactive component, a statement of warning is required to be affixed to the medical device. To account for this rare occasion under § 610.42(a), we estimate that the warning statement would be necessary no more than once a year.

Industry estimates that approximately 13 percent of 10 million donors (1.3 million donors) who come to donate annually are determined not to be eligible for donation before collection because of failure to satisfy eligibility criteria. It is the usual and customary business practice of virtually all 942 collecting establishments to notify on site and to explain the reason why the donor is determined not to be suitable for donating. Based on such information as is available to FDA, we estimate that two-thirds of the 942 collecting establishments provided on site additional information and counseling to a donor determined not to be eligible for donation as usual and customary business practice. Consequently, we estimate that only one-third or 311 collection establishments would need to provide, under § 630.6(a), additional information and counseling onsite to 433,333 (one-third of 1.3 millions) ineligible donors.

It is estimated that another 4.5 percent of 10 million donors (450,000 donors) are deferred annually based on test results. We estimate that currently 95 percent of the establishments that collect 98 percent of the blood and blood components notify donors who have reactive test results for human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), human T-Lymphotropic virus(HTLV), and syphilis as usual and customary business practice. Consequently, 5 percent (47) of the industry (942) collecting 2 percent (9,000) of the deferred donors (450,000) would experience burden related to § 630.6(a). As part of usual and customary business practice, collecting establishments notify an autologous donor's referring physician of reactive test results obtained during the donation process required under § 630.6(d)(1). However, we estimate that 5 percent of the 858 blood collection establishments (43) do not notify the referring physicians of the estimated 2 percent of 300,000 autologous donors with reactive test results (6,000).

FDA has concluded that the use of untested or incompletely tested but

appropriately documented human blood or blood components in rare medical emergencies should not be prohibited. We estimate the recordkeeping under § 610.40(g)(1) to be minimal with one or less occurrence per year. The reporting of test results to the consignee in § 610.40(g) does not create a new burden for respondents because it is the usual and customary business practice or procedure to finish the testing and provide the results to the manufacturer responsible for labeling the blood products.

Section 606.160(b)(1)(ix) requires that establishment to maintain records of the notification efforts. We estimate the total annual records based on the 1.3 million donors determined not to be eligible to donate and each of the 450,000 (1.3 + 450,000 = 1,750,000) donors deferred based on reactive test results for evidence of infection due to communicable disease agents. Under § 606.160(b)(1)(xi), only the 858 registered blood establishments collect autologous donations and, therefore, are required to notify referring physicians. We estimate that 4.5 percent of the 300,000 autologous donors (13,500) will be deferred under § 610.41 and thus result in the notification of their referring physicians.

The hours per response and hours per record are based on estimates received from industry or FDA experience with similar recordkeeping or reporting requirements.

In the **Federal Register** of March 16, 2004 (69 FR 12334), FDA published a 60-day notice requesting public comment on the information collection provisions. We received one comment from the industry on the proposed information collection. The comment stated that they had no reason to believe FDA's burden estimates were not reasonable. Also, the comment did not believe the estimated times constituted a burden on community blood centers.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
610.40(c)(1)(ii)	942	13	12,000	.08	960
610.40(g)(2)	1	1	1	1	1
610.40(h)(2)(ii)(A)	1	1	1	1	1
610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)	40	12	480	0.2	96
610.40(h)(2)(vi)	942	19	18,000	0.08	1,440
610.42(a)	1	1	1	1	1
630.6(a)[2]	311	1,393	433,333	0.08	34,667
630.6(a)[3]	47	191	9,000	1.5	13,500
630.6(d)(1)	43	140	6,000	1	6,000
Total					56,666

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.
[3] Notification of donors deferred based on reactive test results for evidence of infection due to communicable disease agents.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
610.40(g)(1)	858	1	858	0.5	429
606.160(b)(1)(ix)	942	1,858	1,750,000	0.05	87,500
606.160(b)(1)(xi)	858	16	13,500	0.05	675
Total					88,604

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15711 Filed 7–9–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999E–5116]

Determination of Regulatory Review Period for Purposes of Patent Extension; XOPENEX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for XOPENEX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product XOPENEX (levalbuterol). XOPENEX is indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 6 years of age or older with reversible obstructive airway disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for XOPENEX (U.S. Patent No. 5,362,755) from Sepracor, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 30, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of XOPENEX represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for XOPENEX is 1,458 days. Of this time, 824 days occurred during the testing phase of the regulatory review period, while 634 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective: March 30, 1995. The applicant claims February 28, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 30, 1995, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: June 30, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for XOPENEX (NDA 20–837) was initially submitted on June 30, 1997.

3. The date the application was approved: March 25, 1999. FDA has verified the applicant's claim that NDA 20–837 was approved on March 25, 1999.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 502 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by September 10, 2004. Furthermore, any interested person may petition FDA, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 10, 2005. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 21, 2004.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 04–15712 Filed 7–9–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[CFDA Number 93.224; HRSA–05–024]

Fiscal Year 2005 Competitive Application Cycle for Service Area; Competition for the Consolidated Health Center Program (CHCP)

AGENCY: Health Resources and Services Administration, HHS.