promotion programs; administering a national occupational safety and health program; controlling the introduction and spread of infectious diseases; and providing consultation and assistance to other nations and international agencies to assist in improving their disease prevention and control, environmental health, and health promotion activities. CDC carries out these functions through a number of Coordinating Centers/Offices and National Centers and Institutes with expertise and responsibilities in specific areas.

Matters to be Discussed: The agenda will include discussions on program activities, including scientific programs, that will assist in consolidating and refining NCHM vision, mission, goals, organizational structure and expanding and implementing its science for the National Center for Health Marketing; and discussions related to the National Center's role in preparedness, response and recovery with regards to an outbreak of pandemic influenza

Agenda items are tentative and subject to change.

Contact Person for More Information: Dionne R. Mason, Committee Management Specialist, NCHM, 1600 Clifton Road, Mail Stop E–21, Atlanta, Georgia 30333, *Telephone:* (404) 498–2314, Fax (404) 498–2221. The deadline for notification of attendance is November 20, 2008.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: November 4, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. E8–26803 Filed 11–10–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

National Center for Injury Prevention and Control, Initial Review Group, (NCIPC, IRG)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC announces the following meeting for the aforementioned committee:

Times and Date: 1 p.m.–2:30 p.m., December 8, 2008 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92–463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focuses on prevention and control.

Matters to be Discussed: The meeting will include the reporting and voting of the peer reviews conducted in response to Fiscal Year 2008 Requests for Applications related to the following individual research announcements: (1) RFA–CD–08–001, ''Elimination of Health Disparities Through Translation Research (R18)'' and (2) RFA–CE–09–001, ''Grants for the Injury Control Research Centers''. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Rick Waxweiler, PhD, Director, Extramural Research Program Office, NCIPC and Executive Secretary, NCIPC IRG, CDC, 4770 Buford Highway, NE., Mail Stop F–62, Atlanta, Georgia 30341, *Telephone:* (770) 488–4850.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: November 4, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–26801 Filed 11–10–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0345]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and ''Lookback''

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 December 12, 2008.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0116. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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.

Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and ''Lookback'' (OMB Control Number 0910–0116—Extension)

All blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262). Section 351(a) requires that manufacturers of biological products, which include blood and blood components intended for further manufacture into injectable products, have a license, issued upon a demonstration that the product is safe, pure and potent and that the manufacturing establishment meets all applicable standards, including those prescribed in the FDA regulations designed to ensure the continued safety, purity, and potency of the product. In addition, under section 361 of the PHS Act (42 U.S.C. 264), by delegation from the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

Section 351(j) of the PHS Act states that the Federal Food, Drug, and Cosmetic (FD&C) Act also applies to biological products. Blood and blood components for transfusion or for further manufacture into injectable products are drugs, as that term is

defined in section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)). Because blood and blood components are drugs under the act, blood and plasma establishments must comply with the substantive provisions and related regulatory scheme of the FD&C Act. For example, under section 501 of the FD&C Act (21 U.S.C. 351(a)), drugs are deemed ''adulterated'' if the methods used in their manufacturing, processing, packing, or holding do not conform to current good manufacturing practice (CGMP) and related regulations.

The CGMP regulations (part 606) (21 CFR part 606) and related regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components. The public health objective in testing human blood donors for evidence of infection due to communicable disease agents and in notifying donors is to prevent the transmission of communicable disease. For example, the ''lookback'' requirements are intended to help ensure the continued safety of the blood supply by providing necessary information to users of blood and blood components and appropriate notification of recipients of transfusion who are at increased risk for transmitting human immunodeficiency virus (HIV) or hepatitis C virus (HCV) infection.

The information collection requirements in the CGMP, donor testing, donor notification, and ''Lookback'' regulations provide FDA with the necessary information to perform its duty to ensure the safety, purity, and potency of blood and blood components. These requirements establish accountability and traceability in the processing and handling of blood and blood components and enable FDA to perform meaningful inspections. The recordkeeping requirements serve preventive and remedial purposes. The disclosure requirements identify the various blood and blood components and important properties of the product, demonstrate that the CGMP requirements have been met, and facilitate the tracing of a product back to its original source. The reporting requirements inform FDA of any deviations that occur and that may require immediate corrective action.

Under the reporting requirements, § 606.170(b), in brief, requires that facilities notify FDA's Center for Biologics Evaluation and Research (CBER), as soon as possible after confirming a complication of blood collection or transfusion to be fatal. The collecting facility is to report donor fatalities, and the compatibility testing facility is to report recipient fatalities. The regulation also requires the reporting facility to submit a written report of the investigation within 7 days after the fatality. In fiscal years 2006 and 2007, FDA received, on average, 100 of these reports.

Section 610.40(c)(1)(ii) (21 CFR 610.40(c)(1)(ii)), in brief, requires that each donation dedicated to a single identified recipient be labeled as required under § 606.121 and with a label entitled ''INTENDED RECIPIENT INFORMATION LABEL'' containing the name and identifying information of the recipient.

Section 610.40(g)(2) (21 CFR 610.40(g)(2)) requires an establishment to obtain written approval from FDA to ship human blood or blood components for further manufacturing use prior to completion of testing for evidence of infection due to certain communicable disease agents.

Section 610.40(h)(2)(ii)(A) (21 CFR 610.40(h)(2)(ii)(A)), in brief, 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 certain communicable disease agent(s) or collected from a donor with a record of a reactive screening test. Furthermore, § 610.40(h)(2)(ii)(C) and (h)(2)(ii)(D) (21 CFR 610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)), in brief, requires an establishment to label certain reactive human blood and blood components with the appropriate screening test results, and, if they are intended for further manufacturing use into injectable products, include a statement on the label indicating the exempted use specifically approved by FDA. Finally, § 610.40(h)(2)(vi) (21 CFR 610.40(h)(2)(vi)) requires each donation of human blood or blood components, excluding Source Plasma, that tests reactive by a screening test for syphilis and is determined to be a biological false positive to be labeled with both test results.

Section 610.42(a) (21 CFR 610.42(a)) requires a warning statement ''indicating that the product was manufactured from a donation found to be reactive by a screening test for evidence of infection due to the identified communicable disease agent(s)'' in the labeling for medical devices containing human blood or a blood component found to be reactive by a screening test for evidence of infection due to a communicable disease agent(s) or syphilis.

In brief, §§ 610.46 and 610.47 (21 CFR 610.46 and 610.47) require blood collecting establishments to establish, maintain, and follow an appropriate system for performing HIV and HCV prospective ''lookback'' when: (1) A donor tests reactive for evidence of HIV or HCV infection or (2) the collecting establishment becomes aware of other reliable test results or information indicating evidence of HIV or HCV infection (''prospective lookback''). (See §§ 610.46(a)(1) and 610.47(a)(1).) The requirement for ''an appropriate system'' requires the collecting establishment to design standard operating procedures (SOPs) to identify and quarantine all blood and blood components previously collected from a donor who later tests reactive for evidence of HIV or HCV infection, or when the collecting establishment is made aware of other reliable test results or information indicating evidence of HIV or HCV infection. Within 3 calendar days of the donor testing reactive by an HIV or HCV screening test or the collecting establishment becoming aware of other reliable test results or information, the collecting establishment must, among other things, notify consignees to quarantine all identified previously collected in-date blood and blood components (§§ 610.46(a)(1)(ii)(B) and 610.47(a)(1)(ii)(B)) and, within 45 days, notify the consignees of supplemental test results, or the results of a reactive screening test if there is no available supplemental test that is approved for such use by FDA (§§ 610.46(a)(3) and 610.47(a)(3)).

Consignees also must establish, maintain, and follow an appropriate system for performing HIV and HCV ''lookback'' when notified by the collecting establishment that they have received blood and blood components previously collected from donors who later tested reactive for evidence of HIV or HCV infection, or when the collecting establishment is made aware of other reliable test results or information indicating evidence of HIV or HCV infection in a donor (§§ 610.46(b) and 610.47(b)). This provision for a system requires the consignee to establish SOPs for, among other things, notifying transfusion recipients of blood and blood components, or the recipient's physician of record or legal representative, when such action is indicated by the results of the supplemental (additional, more specific) tests or a reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an investigational new drug application (IND) or an investigational device exemption (IDE), is exempted for such use by FDA. The consignee must make reasonable attempts to perform the notification within 12 weeks of receipt

of the supplemental test result or receipt of a reactive screening test result when there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA (§§ 610.46(b)(3) and 610.47(b)(3)).

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 (21 CFR 610.41), or who has been determined not to be eligible as a donor. Section 630.6(d)(1) requires an 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.

Under the recordkeeping requirements, § 606.100(b), in brief, requires that written SOPs be maintained for all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components used for transfusion and further manufacturing purposes. Section 606.100(c) requires the review of all records pertinent to the lot or unit of blood prior to release or distribution. Any unexplained discrepancy or the failure of a lot or unit of final product to meet any of its specifications must be thoroughly investigated, and the investigation, including conclusions and followup, must be recorded.

In brief, § 606.110(a) provides that the use of plateletpheresis and leukapheresis procedures to obtain a product for a specific recipient may be at variance with the additional standards for that specific product if, among other things, the physician certifies in writing that the donor's health permits plateletpheresis or leukapheresis. Section 606.110(b) requires establishments to request prior approval from CBER for plasmapheresis of donors who do not meet donor requirements. The information collection requirements for § 606.110(b) are approved under OMB control number 0910–0338 and, therefore, are not reflected in tables 1 and 2 of this document.

Section 606.151(e) requires that SOPs for compatibility testing include procedures to expedite transfusion in life-threatening emergencies; records of all such incidents must be maintained, including complete documentation justifying the emergency action, which must be signed by a physician.

So that each significant step in the collection, processing, compatibility testing, storage, and distribution of each unit of blood and blood components can be clearly traced, § 606.160 requires that legible and indelible contemporaneous records of each such step be made and maintained for no less than 10 years. Section 606.160(b)(1)(viii) requires records of the quarantine, notification, testing and disposition performed under the HIV and HCV ''lookback'' provisions. Furthermore, § 606.160(b)(1)(ix) requires a blood collection establishment 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.

Section 606.165, in brief, requires that distribution and receipt records be maintained to facilitate recalls, if necessary.

Section 606.170(a) requires records to be maintained of any reports of complaints of adverse reactions arising as a result of blood collection or transfusion. Each such report must be thoroughly investigated, and a written report, including conclusions and followup, must be prepared and maintained. When an investigation concludes that the product caused the transfusion reaction, copies of all such written reports must be forwarded to and maintained by the manufacturer or collecting facility.

Section 610.40(g)(1) (21 CFR 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.

In addition to the CGMP regulations in part 606, there are regulations in part 640 (21 CFR part 640) that require additional standards for certain blood and blood components as follows: Sections 640.3(a)(1), (a)(2), and (f); 640.4(a)(1) and (a)(2); 640.25(b)(4) and (c)(1); 640.27(b); 640.31(b); 640.33(b); 640.51(b); 640.53(b) and (c); 640.56(b) and (d); 640.61; 640.63(b)(3), (e)(1), and (e)(3); 640.65(b)(2); 640.66; 640.71(b)(1); 640.72; 640.73; and 640.76(a) and (b). The information collection requirements and estimated burdens for these regulations are included in the part 606 burden estimates, as described in tables 1 and 2 of this document.

Respondents to this collection of information are licensed and unlicensed blood establishments that collect blood and blood components, including Source Plasma and Source Leukocytes, inspected by FDA, and other transfusion services inspected by Centers for Medicare and Medicaid Services (CMS). Based on information received from CBER's database systems, there are approximately 81 licensed Source Plasma establishments with multiple locations and approximately 2,000 registered blood collection establishments, for an estimated total of 2,081 establishments. Of these establishments, approximately 696 perform plateletpheresis and leukapheresis. These establishments annually collect approximately 28 million units of Whole Blood and blood components, including Source Plasma and Source Leukocytes, and are required to follow FDA ''lookback'' procedures. In addition, there are another 4,980 establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 (formerly referred to as facilities approved for Medicare reimbursement) that transfuse blood and blood components.

The following reporting and recordkeeping estimates are based on information provided by industry, CMS, and FDA experience. Based on information received from industry, we estimate that there are approximately 13 million donations of Source Plasma from approximately 2 million donors and approximately 15 million donations of Whole Blood, including approximately 300,000 (2 percent of 15 million) autologous donations, from approximately 8 million donors. Assuming each autologous donor makes an average of 2 donations, FDA estimates that there are approximately 150,000 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 for evidence of certain communicable disease agents is a licensed product, Source Leukocytes, used in the manufacture of interferon, which requires rapid preparation from blood. Shipments of Source Leukocytes are pre-approved 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 less than one application per year from manufacturers of Source Leukocytes. However, for calculation purposes, we are estimating one application annually.

Under § 610.40(h)(2)(ii)(C) and (h)(2)(ii)(D), FDA estimates that each manufacturer would ship an estimated 1 unit of human blood or blood components per month (12 per year)

that would require 2 labels; one as reactive for the appropriate screening test under § 610.40(h)(2)(ii)(C), and the other stating the exempted use specifically approved by FDA under § 610.40(h)(2)(ii)(D). According to CBER's database system, there are approximately 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: (1) Annually test reactive by a screening test for syphilis, (2) are determined to be biological false positives by additional testing, and (3) are labeled accordingly (§ 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, then a warning statement must 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.

FDA estimates that approximately 3,500 repeat donors will test reactive on a screening test for HIV. We also estimate that an average of three components was made from each donation. Under § 610.46(a)(1)(ii)(B) and (a)(3), this estimate results in 10,500 (3,500 x 3) notifications of the HIV screening test results to consignees by collecting establishments for the purpose of quarantining affected blood and blood components, and another 10,500 (3,500 x 3) notifications to consignees of subsequent test results. We estimate an average of 10 minutes per notification of consignees.

Moreover, we estimate that § 610.46(b)(3) will require 4,980 consignees to notify transfusion recipients, their legal representatives, or physicians of record an average of 0.35 times per year resulting in a total number of 1,755 (585 confirmed positive repeat donors x 3) notifications. Under § 610.46(b)(3), we also estimate 1 hour to accommodate the time to gather test results and records for each recipient and to accommodate multiple attempts to contact the recipient.

Furthermore, we estimate that approximately 7,800 repeat donors per year would test reactive for antibody to HCV. Under § 610.47(a)(1)(ii)(B) and (a)(3), collecting establishments would notify the consignee 2 times for each of the 23,400 (7,800 x 3 components) components prepared from these donations, once for quarantine purposes and again with additional HCV test results for a total of 46,800 notifications as an annual ongoing burden. Under § 610.47(b)(3), we estimate that approximately 4,980 consignees would notify approximately 2,050 recipients or their physicians of record annually. Finally, we estimate 1.0 hours to complete notification.

Industry estimates that approximately 13 percent of 10 million potential donors (1.3 million donors) who come to donate annually are determined not to be eligible for donation prior to collection because of failure to satisfy eligibility criteria. It is the usual and customary business practice of approximately 2,000 blood collecting establishments to notify onsite and to explain why the donor is determined not to be suitable for donating. Based on such available information, we estimate that two-thirds (1,333) of the 2,000 blood collecting establishments provided onsite 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 667, approximately, blood collecting establishments would need to provide, under § 630.6(a), additional information and onsite counseling to the estimated 430,000 (one-third of approximately 1.3 million) ineligible donors.

It is estimated that another 4.5 percent of 10 million potential donors (450,000 donors) are deferred annually based on test results. We estimate that currently approximately 95 percent of the establishments that collect 99 percent of the blood and blood components notify donors who have reactive test results for HIV, Hepatitis B Virus (HBV), HCV, Human T-Lymphotropic Virus (HTLV), and syphilis as usual and customary business practice. Consequently, 5 percent of the 2,081 establishments (104) collecting 1 percent (4,500) of the deferred donors (450,000) would notify donors under § 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 approximately 5 percent of the 2,000 blood collection establishments (100) may not notify the referring physicians of the estimated 2 percent of 150,000 autologous donors with the initial reactive test results (3,000) as their usual and customary business practice.

The recordkeeping chart reflects the estimate that approximately 95 percent of the recordkeepers, which collect 99 percent of the blood supply, have developed SOPs as part of their customary and usual business practice. Establishments may minimize burdens associated with CGMP and related regulations by using model standards developed by industries' accreditation organizations. These accreditation organizations represent almost all registered blood establishments.

Under § 606.160(b)(1)(ix), we estimate the total annual records based on the approximately 1.3 million donors determined not to be eligible to donate and each of the estimated 1.75 million (1.3 million + 450,000) donors deferred based on reactive test results for evidence of infection because of communicable disease agents. Under § 606.160(b)(1)(xi), only the 2,000 registered blood establishments collect autologous donations and, therefore, are required to notify referring physicians. We estimate that 4.5 percent of the 150,000 autologous donors (6,750) will be deferred under § 610.41, which in turn will lead to the notification of their referring physicians.

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 1 or fewer occurrences 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.

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 June 24, 2008 (73 FR 35694) (June 2008 document), FDA published a 60-day notice requesting public comment on the information collection provisions. We received one public comment on the proposed information collection.

The comment cited numerous problems that it stated were caused by the labeling requirement contained in § 610.40(h)(2)(vi), which requires each

donation of human blood or blood components, excluding Source Plasma, that tests reactive by a screening test for syphilis and is determined to be a biological false positive to be labeled with both test results. For example, the comment stated that the labeling requirement ''causes unnecessary work and interrupts routine operations, thereby introducing risk of error, with no increase in safety.'' The comment also stated that the requirement ''generates inappropriate concerns on the part of healthcare personnel, transfusion recipients and their families.'' The comment asked that this requirement be deleted. These concerns pertain to matters that are outside the scope of the proposed information collection. Consequently, we decline to adopt the comment's recommendations.

The comment also questioned FDA's estimate of 5 minutes in connection with § 610.40(h)(2)(vi). We had estimated that the time associated with the labeling requirement contained in this rule was 5 (4.8) minutes. The comment stated, ''Any non-routine activity that interrupts normal labeling operations, [sic] causes delays that take more than 4.8 minutes.'' The comment later went on to acknowledge that the application of a label to a unit, which is only one step in the labeling process, may take only five minutes. We wish to clarify that we only are referring to the application of a label to a unit in this proposed information collection. Therefore, consistent with the comment, our estimate remains the same.

Moreover, the comment referred to page 35697 and table 1 of the June 2008 document, and stated that ''FDA estimated that labeling directed and reactive or untested units for shipment would take five minutes. If labeling refers only to the application of the label to the unit, which is only one step in the labeling process, then 5 minutes may be adequate.'' We are unclear what the comment is referring to on page 35697 of the June 2008 document and note that table 1 refers to an estimate of 0.08 (4.8 minutes) with respect to §§ 610.40(c)(1)(ii), 610.40(h)(2)(vi), and 630.6(a). We are assuming that the comment is referring to the first two regulations, as the third goes to donor notification. We wish to clarify that in this information collection, we are only referring to the application of the label to the unit. Therefore, consistent with the comment, our estimate remains the same.

Finally, the comment pointed out an error in calculation of total hours associated with § 606.160(b)(1)(ix) in table 2 of the June 2008 document. The total hours calculated was listed as 875,000, instead of 87,500 (0.05 x 1,750,000). Therefore, the total estimated recordkeeping burden is 362,426. We have corrected this error accordingly.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
606.170(a)	353[5]	1.20	424	0.5	212
606.170(b)[2]	100	1	100	20	2,000
610.40(c)(1)(ii)	2,081	5.77	12,000	0.08	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)	2,081	8.65	18,000	0.08	1,440
610.42(a)	1	1	1	1	1
610.46(a)(1)(ii)(B)	2,000	5.25	10,500	0.17	1,785
610.46(a)(3)	2,000	5.25	10,500	0.17	1,785
610.47(b)(3)	4,980	0.41	2,050	1.0	2,050
610.47(a)(1)(ii)(B)	2,000	11.70	23,400	0.17	3,978
610.47(a)(3)	2,000	11.70	23,400	0.17	3,978
610.47(b)(3)	4,980	0.41	2,050	1.0	2,050
630.6(a)[3]	667	644.68	430,000	0.08	34,400
630.6(a)[4]	104	43.27	4,500	1.5	6,750
630.6(d)(1)	100	30	3,000	1	3,000
Total					64,487

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The reporting requirement in § 640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for § 606.170(b).
[3]Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.
[4]Notification of donors deferred based on reactive test results for evidence of infection due to communicable disease agents.
[5]Five percent of establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 that transfuse blood and components and FDA-registered blood establishments (0.05 x 4,980 + 2,081).

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
606.100(b)[2]	353[5]	1	353	24	8,472
606.100(c)	353[5]	10	3,530	1	3,530
606.110(a)[3]	35[6]	1	35	0.5	18
606.151(e)	353[5]	12	4,236	0.083	352
606.160[4]	353[5]	793.20	280,000	0.75	210,000
606.160(b)(1)(viii)					
HIV consignee notification	2,000	10.50	21,000	.17	3,570
	4,980	4.21	21,000	.17	3,570
HCV consignee notification	2,000	23.40	46,800	.17	7,956
	4,980	9.4	46,800	.17	7,956
HIV recipient notification	4,980	0.35	1,755	.17	298
HCV recipient notification	4,980	0.41	2,050	.17	349
606.160(b)(1)(ix)	2,081	840.94	1,750,000	0.05	87,500
606.160(b)(1)(xi)	2,000	3.375	6,750	0.05	338
606.165	353[5]	793.20	280,000	0.083	23,240
606.170(a)	353[5]	12	4,236	1.00	4,236
610.40(g)(1)	2,081	1	2,081	0.50	1,041
Total					362,426

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The recordkeeping requirements in §§ 640.3(a)(1), 640.4(a)(1), and 640.66, which address the maintenance of SOPs, are included in the estimate for § 606.100(b).
[3]The recordkeeping requirements in § 640.27(b), which address the maintenance of donor health records for the plateletpheresis, are included in the estimate for § 606.110(a).
[4]4 The recordkeeping requirements in §§ 640.3(a)(2) and (f); 640.4(a)(2); 640.25(b)(4) and (c)(1); 640.31(b); 640.33(b); 640.51(b); 640.53(b) and (c); 640.56(b) and (d); 640.61; 640.63(b)(3), (e)(1), and (e)(3); 640.65(b)(2); 640.71(b)(1); 640.72; and 640.76(a) and (b), which address the maintenance of various records are included in the estimate for § 606.160.
[5]Five percent of establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 that transfuse blood and components and FDA-registered blood establishments (0.05 x 4,980 + 2,081).
[6]Five percent of plateletpheresis and leukopheresis establishments (0.05 x 696).

Dated: November 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26863 Filed 11–10–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0039]

Notice of Approval of Original Abbreviated New Animal Drug Application; Phenylbutazone Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved an original abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for veterinary prescription use of phenylbutazone tablets in horses for the relief of inflammatory conditions associated with the musculoskeletal system.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200–433 providing for veterinary prescription use of Phenylbutazone Tablets in horses for the relief of inflammatory conditions associated with the musculoskeletal system. First Priority, Inc.'s, ANADA for Phenylbutazone Tablets is approved as a generic copy of First Priority, Inc.'s, PRIBUTAZONE Tablets, approved under NADA 48–647. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and part 514 (21 CFR part 514), in §§ 514.105(a) and 514.106(a), the Center for Veterinary Medicine is providing notice that this ANADA is approved as of October 23, 2008.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets