requests for fast track designation to the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research is approximately 97, and the number of requests received is approximately 118 annually. FDA estimates that the number of hours needed to prepare a request for fast track designation is approximately 60 hours per request.

Not all requests for fast track designation may meet the statutory standard. Of the requests for fast track designation made per year, the Agency granted 77 requests from 64 respondents, and for each of these granted requests a premeeting package was submitted to the Agency. FDA estimates that the preparation hours are approximately 100 hours per premeeting package.

In the **Federal Register** of April 13, 2011 (76 FR 20679), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Reporting activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Designation Requests	97	1.22	118	60	7,080
Premeeting Packages	64	1.20	77	100	7,700
Total					14,780

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

Dated: July 19, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–19138 Filed 7–27–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0511]

Agency Information Collection Activities; Proposed Collection; 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 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 collection of information requirements relating to FDA's regulation of current good manufacturing practice (CGMP) and related regulations for blood and blood components; and requirements for donor testing, donor notification, and ''lookback.''

DATES: Submit either electronic or written comments on the collection of information by September 26, 2011.

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: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.vilela@fda.hhs.gov*.

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.

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) of the PHS Act 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 Act (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 FD&C 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 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 certain information 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 year 2010, FDA received 76 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 containing the name and identifying information of the recipient.

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 prior to completion of testing for evidence of infection due to certain communicable disease agents.

Section 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), in brief, require 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, to include a statement on the label indicating the exempted use specifically approved by FDA. Finally, § 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 leukaphesis 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) 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 the Centers for Medicare and Medicaid Services (CMS). Based on information received from CBER's database systems, there are approximately 31 licensed Source Plasma establishments with multiple locations and approximately 1,675 registered blood collection establishments, for an estimated total of 1,706 establishments. Of these establishments, approximately 1,032 perform plateletpheresis and leukopheresis. These establishments annually collect approximately 38.3 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 4,059 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 21 million donations of Source Plasma from approximately 2 million donors and approximately 17.3 million donations of Whole Blood, including approximately 261,000 (approximately 1.5 percent of 17.3 million) autologous donations, from approximately 10.9 million donors. Assuming each autologous donor makes an average of 2 donations, FDA estimates that there are approximately 130,500 autologous donors.

FDA estimates that approximately 5 percent (3,600 of the 72,000 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), Source Leukocytes, a licensed product that is used in the manufacture of interferon, which requires rapid preparation from blood, is currently shipped prior to completion of testing for evidence of certain communicable disease agents. 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 × 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 × 3) notifications to consignees of subsequent test results. We estimate an average of 10 minutes per notification of consignees.

We estimate that § 610.46(b)(3) will require 4,059 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 × 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 × 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 4,059 consignees would notify approximately 2,050 recipients or their physicians of record annually. Finally, we estimate 1 hour to complete notification.

Based on industry estimates, roughly 13 percent of approximately 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 1,675 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 (1,117) of the 1,675 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 558, approximately, blood collecting establishments would need to provide, under § 630.6(a), additional information and onsite counseling to the estimated 433,000 (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 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 1,706 establishments (85) 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 1,675 blood collection establishments (84) may not notify the referring physicians of the estimated 2 percent of 130,500 autologous donors with the initial reactive test results (2,610) 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 1,675 registered blood establishments collect autologous donations and, therefore, are required to notify referring physicians. We estimate that 4.5 percent of the 130,500 autologous donors (5,872) 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 one 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
606.170(a)	[5] 288	1.20	346	0.5	173
606.170(b) [2]	76	1	76	20	1,520
610.40(c)(1)(ii)	1,706	2.11	3,600	0.08	288
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)	1,706	10.55	18,000	0.08	1,440
610.42(a)	1	1	1	1	1
610.46(a)(1)(ii)(B)	1,675	6.27	10,500	0.17	1,785
610.46(a)(3)	1,675	6.27	10,500	0.17	1,785
610.46(b)(3)	4,059	0.43	1,755	1	1,755
610.47(a)(1)(ii)(B)	1,675	13.97	23,400	0.17	3,978
610.47(a)(3)	1,675	13.97	23,400	0.17	3,978
610.47(b)(3)	4,059	0.51	2,050	1	2,050
630.6(a) [3]	558	775.98	433,000	0.08	34,640
630.6(a) [4]	85	52.94	4,500	1.5	6,750
630.6(d)(1)	84	31.07	2,610	1	2,610
Total					62,851

[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 ($0.05 \times 4,059 + 1,706$).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
606.100(b) [2]	[5] 288	1	288	24	6,912
606.100(c)	[5] 288	10	2,880	1	2,880
606.110(a) [3]	[6] 52	1	52	0.5	26
606.151(e)	[5] 288	12	3,456	0.08	276
606.160 [4]	[5] 288	1,329.86	383,000	0.75	287,250
606.160(b)(1)(viii)					
HIV consignee notification	1,675	12.54	21,000	0.17	3,570
	4,059	5.17	21,000	0.17	3,570
HCV consignee notification	1,675	27.94	46,800	0.17	7,956
	4,059	11.53	46,800	0.17	7,956
HIV recipient notification	4,059	0.43	1,755	0.17	298
HCV recipient notification	4,059	0.51	2,050	0.17	349
606.160(b)(1)(ix)	1,706	1,025.79	1,750,000	0.05	87,500
606.160(b)(1)(xi)	1,675	3.51	5,872	0.05	294
606.165	[5] 288	1,329.86	383,000	0.08	30,640
606.170(a)	[5] 288	12	3,456	1	3,456
610.40(g)(1)	1,706	1	1,706	0.50	853
Total					443,786

[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] 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 ($0.05 \times 4,059 + 1,706$).
[6] Five percent of plateletpheresis and leukopheresis establishments ($0.05 \times 1,032$).

Dated: July 22, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–19040 Filed 7–27–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0318]

Determination That INVERSINE (Mecamylamine Hydrochloride) Tablet and Six Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the seven drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6308, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is withdrawn from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicant, FDA withdrew approval of NDA 021039 for AGENERASE (amprenavir) Oral Solution in the **Federal Register** of July 21, 2010 (75 FR 42455).)

Application No.	Drug	Applicant
NDA 010251	INVERSINE (mecamylamine hydrochloride (HCl)) Tablet, 2.5 milligrams (mg).	Targacept, Inc., 200 East 1st St., Suite 300, Winston Salem, NC 27101–4165
NDA 011552	STELAZINE (trifluoperazine HCl) Injection, Equivalent to (EQ) 2 mg base/milliliter (mL).	GlaxoSmithKline, 5 Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709–3398
NDA 011552	STELAZINE (trifluoperazine HCl) Oral Concentrate, EQ 10 mg base/mL.	Do.
NDA 016798	SINEQUAN (doxepin HCl) Capsules, EQ 10 mg base, EQ 25 mg base, EQ 50 mg base, EQ 75 mg base, EQ 100 mg base, and EQ 150 mg base.	Pfizer Laboratories, Division of Pfizer Inc., 235 East 42nd St., New York, NY 10017
NDA 017516	SINEQUAN (doxepin HCl) Oral Concentrate, EQ 10 mg base/mL.	Do.
NDA 019201	VOLTAREN (diclofenac sodium) Delayed-Release Tablet, 75 mg.	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936–1080
NDA 021039	AGENERASE (amprenavir) Oral Solution, 15 mg/mL	GlaxoSmithKline

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 25, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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