Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) (42 U.S.C. 9601 et seq.) by establishing certain responsibilities for the ATSDR and the Environmental Protection Agency (EPA) with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these responsibilities is that the Administrator of ATSDR prepare toxicological profiles for substances included on the priority lists of hazardous substances. These lists identified 275 hazardous substances that ATSDR and EPA determined pose the most significant potential threat to human health. The availability of the revised priority list of 275 hazardous substances was announced in the **Federal Register** on November 17, 1997 (62 FR 61332). For prior versions of the list of substances see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); and April 29, 1996 (61 FR 18744). [CERCLA also requires ATSDR to assure the initiation of a research program to fill data needs associated with the substances.]

Section 104(i)(3) of CERCLA [42 U.S.C. 9604(i)(3)] outlines the content of these profiles. Each profile will include an examination, summary and interpretation of available toxicological information and epidemiologic evaluations. This information and these data are to be used to identify the levels of significant human exposure for the substance and the associated health effects. The profiles must also include a determination of whether adequate information on the health effects of each substance is available or in the process of development. When adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of research to determine these health effects.

Although key studies for each of the substances were considered during the profile development process, this **Federal Register** notice seeks to solicit any additional studies, particularly unpublished data and ongoing studies, which will be evaluated for possible addition to the profiles now or in the future.

The following draft toxicological profiles will be made available to the public on or about October 17, 1998.

Document	Hazardous substance	CAS No.
1	Arsenic	007440–38–2
	Dimethylarsenic Acid.	000075–60–5
2	Chromium	007440–47–3
	Chromium, Hexavalent.	018540–29–9
		007789–09–5
		013765–19–0
		001333–82–0
		007758–97–6
		007789–00–6
		007778–50–9
		007775–11–3
		007789–06–2
		013530–65–9
3	Endosulfan	000115–29–7
	Endosulfan, alpha	000959–98–8
	Endosulfan, sulfate	001031–07–8
	Endosulfan, beta ..	033213–65–9
4	Ethion	000563–12–2
5	Methylene Chloride	000075–09–2
6	Toluene	000108–88–3

All profiles issued as ''Drafts for Public Comment'' represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information which may be used to supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our clients.

Dated: October 15, 1998.

Donna Garland,

Acting Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 98–28184 Filed 10–20–98; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0143]

Agency Emergency Processing Request Under OMB Review

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns procedures recommended in a guidance entitled ''Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV.''

DATES: Submit written comments on the collection of information by November 2, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: With respect to the following collection of information, FDA invites comments on: (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.

Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance entitled ''Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and

Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV.'' The guidance document provides recommendations for donor screening and supplemental testing for antibody to HCV, quarantine of prior collections from a donor who later tests repeatedly reactive for antibody to HCV, and notification and counseling of recipients of blood and blood components at increased risk for transmitting HCV. The statutory authority to collect this information is provided under sections 351 and 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262 and 264) and the provisions of the Federal Food, Drug, and Cosmetic Act that apply to drugs (21 U.S.C. 201 *et seq.*). The purpose of this guidance is to help ensure the continued safety of the blood supply by preventing the introduction, transmission, and spread of HCV. The collection of information described in the guidance will help ensure that important information is provided to consignees and recipients of blood and blood components from a donor who later tests positive for HCV. Also, the collection of information will enable consignees to identify and quarantine product that may be at increased risk for transmitting HCV. As a result, transfusion recipients of such product may have the opportunity to seek medical counseling.

Lookback (product retrieval and recipient notification) related to hepatitis B virus (HBV), HCV, and human T-lymphotropic virus (HTLV–I) testing has been discussed at open public meetings, including meetings of FDA's Blood Products Advisory Committee, on multiple occasions since October 1989. As a response to these discussions, FDA provided detailed guidance in the July 19, 1996, memorandum on the quarantine and disposition of certain prior collections of blood and blood components from donors who subsequently test repeatedly reactive for hepatitis B surface antigen (HBsAg), antibody to hepatitis B core antigen (anti-HBc), anti-HCV, or antibody to HTLV type I (anti-HTLV–I). The memorandum recommended that blood establishments notify consignees (such as the transfusion service, physician, fractionator, etc.) for the purpose of quarantine and eventual disposition of products made from prior collections. At that time, FDA did not recommend notification of recipients of blood from donors who subsequently test positive for anti-HCV, because no clear consensus on the public health benefit of such action had emerged.

Improvements in the treatment and management of HCV infections have occurred recently, and at public meetings on April 24 and 25, 1997, and August 11 and 12, 1997, the PHS Advisory Committee on Blood Safety and Availability discussed recipient notification related to hepatitis C. Consistent with recommendations of the Public Health Service Advisory Committee, in the **Federal Register** of March 20, 1998 (63 FR 13675), FDA issued a guidance regarding such notification for implementation and comment. In response to comments received, FDA is now issuing the previously referenced guidance, which supersedes the guidance issued on July 19, 1996, and replaces the guidance issued on March 20, 1998.

Description: This guidance recommends that blood establishments prepare and follow written procedures when blood establishments have collected Whole Blood, blood components, Source Plasma, and Source Leukocytes later determined to be at risk for transmitting HCV infections. This guidance provides recommendations, similar to the requirements now in effect for HIV ''Lookback'' (21 CFR 610.46 and 610.47), to clarify the status of the donor who later tests repeatedly reactive for HCV, to quarantine prior collections from such donors, and to notify transfusion recipients, as appropriate, based on further testing of the donor. The guidance recommends that when a donor who previously donated blood is tested in accordance with this guidance on a later donation, and tests repeatedly reactive for antibody to HCV, the blood establishment should perform a supplemental test using a licensed test, and notify consignees who received Whole Blood, blood components, Source Plasma, and Source Leukocytes from prior collections so that appropriate action is taken. The guidance document recommends that blood establishments and consignees quarantine previously collected Whole Blood, blood components, Source Plasma and Source Leukocytes from such donors, and if appropriate, consignees should notify transfusion recipients. In addition to the prospective ''lookback'' recommendations that are similar to the ''lookback'' requirements for HIV, this guidance recommends a retrospective review of testing records that should identify prior collections from donors at increased risk for transmitting HCV as far back as 10 years. Under this guidance, it is suggested that blood establishments notify consignees of the risk of HCV transmission that exists for prior collections based on the retrospective review of record and the results of the supplemental testing performed before or as a result of the retrospective review of records. In addition, the guidance recommends that blood establishments notify consignees of the risk of HCV transmission that exists for prior collections from a donor who tested repeatedly reactive on a screening test for HCV and has no record of further testing and now cannot be clarified because further testing is impractical or infeasible. This guidance recommends that blood establishments maintain records of the source and disposition of all units of blood and blood products for at least 10 years from the date of disposition or 6 months after the latest product expiration date, whichever is the later date. Under 21 CFR 606.160, such records are required to be retained for 5 years. FDA is recommending an extended records retention period because advances in medical diagnosis and therapy have created opportunities for disease prevention or treatment many years after recipient exposure to a donor later determined to be at increased risk for transfusion-transmitted disease. Additionally, methods of recordkeeping have advanced, improving the ability of blood establishments to more easily maintain and retrieve records. Also, this guidance recommends that any consignee of a blood establishment notify the transfusion recipients of blood and blood components at increased risk for transmitting HCV.

The agency is issuing this guidance to promote the continued safety of the blood supply, to help provide users with critical information about blood and blood components, and to promote notification to transfusion recipients regarding receipt of blood and blood components at risk for transmitting HCV.

Description of Respondents: Blood establishments (Business and Not-for-Profit) and consignees of blood establishments, including hospitals, transfusion services, and physicians.

The total reporting and recordkeeping burden is estimated to be 285,867 hours. However, of this total approximately 268,374 hours would be expended on a one-time basis for establishing the written procedures and doing the one-time retrospective review of records. Therefore, 17,493 hours is estimated as the ongoing annual burden related to this guidance. The total ongoing

prospective annual burden for blood establishments is estimated to be 12,630 hours. The prospective annual burden for consignees of blood establishments is estimated to be 4,863 hours.

The burden estimates are based on Health Care Financing Administration (HCFA) and FDA registration records and the following estimates from the Centers for Disease Control and Prevention (CDC). CDC estimates there are approximately 9,750,127 donations from repeat donors per year and the prevalence of HCV among donors is 0.27 percent. Therefore, CDC estimates that 26,325 repeat donors per year could test repeatedly reactive for HCV. For each of these donors, the recommendations in this guidance call for blood establishments to notify the consignee (transfusion service) two times (once for quarantine purposes and again with supplemental test results) for a total 52,650 notifications as an annual ongoing burden. Based on estimates from CDC, FDA expects that for the one-time review of records, as many as 237,688 blood products would be at increased risk for transmitting HCV. Therefore, FDA estimates that for each of these products, blood establishments should notify consignees to quarantine these products, should report supplemental test results to consignees, and consignees should notify recipients or the recipients' attending physician. The guidance recommends that blood establishments notify the consignees two times (once for quarantine purposes and again with supplemental test results) for a total of 475,376 notifications as a result of the retrospective review. The total annual responses for blood establishments is estimated to be the combined number of notifications (475,376 + 52,650) or 528,026. FDA estimates the amount of time for each notification of a consignee by a blood establishment will be approximately 12 minutes (0.2 hours). Consequently, the total estimated reporting burden hours for blood establishments is (528,026 report notifications x 0.2 hrs) 105,605 hours. However, the ongoing annual burden not associated with the retrospective review would be 10,530 hours (52,650 x 0.2 hours).

CDC expects that approximately 2,730 repeat donors who have repeatedly reactive HCV screening test results will confirm positive for HCV each year. Based on CDC's research and information, a donor who confirms positive for HCV will have donated on the average only two previous times and on the average only 1.6 components will have been made from each donation. Based on this information, there could be 8,736 transfusion recipients that should be notified per year (2,730 repeat donors per year that confirm positive for HCV x 2 prior donations per donor x 1.6 components per donation). Thus, the total notifications by consignees is estimated to be 246,424 annually (8,736 transfusion recipients who may be at increased risk of transmitting HCV plus the estimated 237,688 transfusion recipients identified from a retrospective review). The time estimated for consignees to make a notification is 30 minutes or 0.5 hours on average. This time, which is somewhat longer than for blood establishments to notify consignees, allows for the possibility of having to make up to three attempts to complete the notification process and creates a total reporting burden of 123,212 hours. However, the ongoing annual reporting burden for consignees is expected to be only 4,368 hours (8,736 recipients per year x 0.5 hours). According to the HCFA, there are approximately 6,200 consignees that should be responsible for notification.

In the recordkeeping Table 2 of this document, the 8.75 hours per blood establishment recordkeeper represents 8 hours to develop written procedures for the HCV lookback recommendations and 0.75 hours to update 9 HCV repeat reactive records (frequency of recordkeeping is 10 less 1 written procedure = 9 HCV testing records on average). FDA estimates that it takes approximately 5 minutes to update each record (9 x 5 minutes = 45 minutes or 0.75 hours per recordkeeper). Therefore, the total recordkeeping by blood establishments is estimated to be 24,500 hours. Likewise, the 5.25 hours per consignee recordkeeper includes 2 hours to develop written procedures for the HCV lookback notification process and 3.25 hours to update 39 transfusion recipient records (frequency of consignee recordkeeping is 40 less 1 written procedure = 39 recipient records on average). FDA estimates that it takes approximately 5 minutes to update each record (39 x 5 minutes = 195 minutes or 3.25 hours). Therefore, the total recordkeeping burden for consignees is estimated to be 32,550. The combined total recordkeeping burden for both blood establishments and consignees is estimated to be 57,050 hours. However, based on the prospective number of repeat donors per year and the number that confirm positive for HCV, the ongoing annual recordkeeping burden may only be 2,596 hours. Over time we expect the ongoing annual recordkeeping burden to decline much as the prevalence of HCV among donors has declined due to the implementation of screening tests for anti-HCV which helps to reduce the number of donors infected with HCV from the donor pool.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Collection Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Blood Establishments	2,800	38	528,026	.2	105,605
Consignees	6,200	40	246,424	.5	123,212
Total					228,817

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Collection Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Blood Establishments	2,800	10	29,125	8.75	24,500
Consignees	6,200	40	252,624	5.25	32,550

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

Collection Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Total					57,050

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

Maintenance costs were not estimated for the additional maintenance of records beyond the current 5 years to the recommended 10 years, because modern storage technology has markedly reduced the space needed to store records.

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. Because HCV frequently causes chronic infection of the liver, it can cause serious liver injury and can be life threatening, and because new therapies are recently available, it is essential to the agency's mission of protecting and promoting the public health that this guidance be made available to the public immediately. The information is needed immediately to replace the March 20, 1998, guidance that was withdrawn September 8, 1998. The use of normal clearance procedures could take 180 days or more, during which time guidance would not be in place, thus disrupting or preventing this collection of information.

Dated: October 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28218 Filed 10–20–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0811]

Agency Emergency Processing Request Under OMB Review

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns the submission by sponsors of investigational new drugs and applicants for new drug approvals or biological licenses under the Federal Food, Drug, and Cosmetic Act (the act) and the guidance for industry on fast track drug development programs.

DATES: Submit written comments on the collection of information by November 5, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION:

I. Guidance for Industry

FDA is preparing a guidance entitled ''Guidance for Industry: Designation, Development, and Application Review for Products in Fast Track Drug Development Programs.'' The guidance will provide the agency's interpretation of terms central to FDA's fast track programs and the agency's views on information that should accompany fast track program submissions.

With respect to the following collection of information, FDA invites comment on: (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.

Guidance for Industry: Designation, Development, and Application Review for Products in Fast Track Drug Development Programs

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amends the act by adding section 506 (21 U.S.C. 356) and authorizes FDA to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrate a potential to meet an unmet medical need. The issuance of the guidance will be under section 112(b) of FDAMA, which requires the agency to issue guidance regarding fast track policies and procedures within 1 year of the date of enactment of FDAMA, November 21, 1997. The guidance will discuss collections of information that are expressly specified under section 506 of the act, other sections of the Public Health Service Act (PHS Act), or implementing regulations. For example, under section 506 of the act, an applicant who seeks fast track designation must submit a request to FDA. Some of the support for such a request may be required under regulations, such as parts 312, 314, and 601 (21 CFR parts 312, 314, and 601), which specify the types and format of information and data that should be submitted to FDA for evaluation of the safety and effectiveness of investigational new drug applications (IND's) (part 312), new drug applications (part 314), or biological license applications (part 601). The guidance will describe three general areas involving collection of information: Designation requests, pre-meeting packages, and requests to submit portions of an application. Of these, designation requests, and pre-meeting packages in support of obtaining a fast track program benefit will provide for additional collections of information not provided elsewhere in statute or regulation. Information in support of fast track designation or fast track program benefits that has previously been submitted to the agency, may, in some cases, be incorporated by referring to them rather