DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[INFO–99–41]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments Are Invited on

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Collaborative US–Mexico Border Diabetes Prevention and Control Project—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)—The Pan American Health Organization (PAHO), El Paso field office, and the United States-Mexico Border Health Association (USMBHA) in collaboration with the United States/Mexico Border Diabetes Prevention and Control Project Work Group (USMBDPCP) is requesting funds for a binational diabetes prevention and control project on the United States-Mexico border that begins with an evaluation of the burden of diabetes on the border (Phase 1) and expands into a program implementation (Phase 2), using the results from Phase 1. This proposed project is responding to President Clinton's Initiative on Racial and Ethnic Health Disparities, as well as the Mexican Secretariat Adult and Elderly Health Program strategy in which diabetes is a national health priority. Diabetes has also been declared a binational border priority by the USMBHA General Assembly in a resolution to develop diabetes control infrastructure on the border.

The purpose of the project is to diminish the impact of diabetes on the border population by conducting activities in two related and chronological phases (prevalence study and intervention program). Phase 1 will assess the prevalence of diabetes, related behavioral risk factors, and assess the health services for the border population. The information collected through this household survey will serve as a guide for the development of diabetes education and training activities in Phase 2. These programs will be culturally appropriate and will include the participation of community health workers (promotores) and primary healthcare providers. Initial planning and promotional activities needed for Phase 2 will take place concurrent with Phase 1.

Activities for years two through five will include implementation of community interventions, capacity building, and program evaluation. The household survey will be repeated in the fifth year of the project.

The PAHO/USMBHA and the USMBDPCP Work Group have obtained considerable financial support for this proposed project. The total cost to CDC is estimated at: $735,630.

Respondents	Number. of respondents	Number of responses/respondent	Average burden of response (hours)	Total burden (hours)
Individual within Household	3,770	1	0.40	1508

Dated: September 17, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–24784 Filed 9–22–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4006]

Beecham Laboratories et al.; Withdrawal of Approval of 44 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 44 abbreviated new drug applications (ANDA's). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: September 23, 1999.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

ANDA No.	Drug	Applicant
60–680	Ampicillin for Oral Suspension, 125 milligrams (mg)/5 milliliters (mL) and 250 mg/5 mL.	Beecham Laboratories, 1 Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101–7929.
60–922	Neomycin Sulfate-Hydrocortisone Topical Ointment.	Teva Pharmaceuticals, USA, 1510 Delp Dr., Kulpsville, PA 19443.
61–598	Ampicillin Trihydrate Capsules USP, 250 mg and 500 mg.	Pharmacia & Upjohn, 7000 Portage Rd., Kalamazoo, MI 49001–0199.
61–599	Ampicillin Trihydrate for Oral Suspension USP, 125 mg/5 mL and 250 mg/5 mL.	Do.
61–934	Sterile Ampicillin Sodium USP.	Bristol-Myers Squibb Pharmaceutical Research Institute, P.O. Box 4000, Princeton, NJ 08543–4000.
61–935	Penicillin G Sodium for Injection USP, 5,000,000 units per vial.	Do.
62–425	Bacitracin-Polymyxin B Sulfate-Neomycin Sulfate Topical Ointment.	Blistex Inc., 1800 Swift Dr., Oak Brook, IL 60532–1574.
62–595	Neomycin Sulfate-Triamcinolone Acetonide Cream.	Pharmaderm, Division of Altana Inc., 60 Baylis Rd., Melville, NY 11747.
62–600	Neomycin Sulfate-Triamcinolone Acetonide Cream.	E. Fougers & Co., Division of Altana Inc., 60 Baylis Rd., Melville, NY 11747.
62–608	Neomycin Sulfate-Tramcinolone Acetonide Ointment.	Do.
62–609	Neomycin B Sulfate and Triamcinolone Acetonide Ointment.	Savage Laboratories, Inc., Division of Altana Inc., 60 Baylis Rd., Melville, NY 11747.
71–497	Anticoagulant Citrate Dextrose Solution USP.	Miles, Inc., 800 Dwight Way, Berkeley, CA 94701–1986.
72–374	PORTALAC (Lactulose Solution USP) 10 g/15 mL.	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
80–414	Lidocaine Hydrochloride Injection USP, 1% and 2%.	Miles, Inc.
80–415	Procaine Hydrochloride Injection USP, 1% and 2%.	Do.
80–570	Cyanocobalamin Injection USP, 1,000 micrograms (mcg)/mL.	Savage Laboratories, Inc.
80–982	Ergocalciferol Capsules USP.	Pharmacia & Upjohn.
81–274	Hydrocortisone Acetate Cream 1%.	Able Laboratories Inc., 6 Hollywood Ct., South Plainfield, NJ 07080.
84–059	Hydrocortisone Cream 1%	G&W Laboratories, Inc., 111 Coolidge St., South Plainfield, NJ 07080–3895.
84–438	Meprobamate Tablets USP, 400 mg.	Pharmavite Corp., 15451 San Fernando Mission Blvd., P.O. Box 9606, Mission Hills, CA 91346–9606.
84–463	Ethchlorvynol Capsules USP, 100, 200, 500, and 750 mg.	Banner Gelatine Products Corp., 4125 Premier Dr., P.O. Box 2210, High Point, NC 27261–2210.
84–573	DERMACORT (Hydrocortisone Lotion USP) 0.5%.	Solvay Pharmaceuticals, Inc.
84–662	Prednisone Tablets USP, 5 mg.	Pharmavite Corp.
84–663	Reserpine Tablets USP, 0.25 mg.	Do.
84–664	Prednisolone Tablets USP, 5 mg.	Do.
84–693	Prophoxyphene Hydrochloride Capsules USP, 32 mg and 65 mg.	Do.
84–707	Triamcinolone Tablets, 8 mg.	Roxane Laboratories, Inc., P.O. 16532, Columbus, OH 43216–6532.
84–709	Triamcinolone Tablets, 4 mg.	Do.
84–991	DEXONE (Dexamethasone Tablets USP) 0.5 mg.	Solvay Pharmaceuticals, Inc.
84–992	DEXONE (Dexamethasone Tablets USP) 4 mg.	Do.
84–993	DEXONE (Dexamethasone Tablets USP) 0.75 mg.	Do.
85–024	Triproldine Hydrochloride and Pseudophedrine Hydrochloride Tablets, 2.5 mg/60 mg.	MD Pharmaceuticals, Inc., 3501 W. Garry Ave., Santa Ana, CA 92704.
85–134	Acetaminophen Tablets, 325 mg and Oxycodone/Acetaminophen Tablets (Oxycodone Hydrochloride 4.5 mg, Oxycodone Terephthalate 0.38 mg, Acetaminophen 325 mg).	Bristol-Myers Squibb Co., Pharmaceutical Group, P.O. Box 4755, Syracuse, NY 13221–4755.
85–685	PROVAL #3 (Acetaminophen and Codeine Phosphate) Capsules, 325 mg/30 mg.	Solvay Pharmaceuticals, Inc.
85–893	UNIPRES (Reserpine, Hydralazine Hydrochloride, and Hydrochlorothiazine) Tablets (peach) 0.1/25/15 mg.	Do.
85–999	ORASONE (Prednisone Tablets USP) 50 mg.	Do.
86–296	Folic Acid 1 mg.	Vintage Pharmaceuticals, Inc., 3241 Woodpark Blvd., Charlotte, NC 28206.
86–462	DERMACORT (Hydrocortisone Lotion USP) 1%.	Solvay Pharmaceuticals, Inc.
87–213	Hydralazine Hydrochloride and Hydrochlorothiazide Capsules, 50 mg/50 mg.	Do.
87–228	Chloroquine Phosphate Tablets.	MD Pharmaceuticals, Inc.
87–566	Cyproheptadine Hydrochloride Tablets, 4 mg.	Do.
87–608	Hydralazine Hydrochloride and Hydrochlorothiazide Capsules 25 mg/25 mg.	Solvay Pharmaceuticals, Inc.
88–376	Reserpine, Hydralazine Hydrochloride, and Hydrochlorothiazide Tablets USP, 0.1 mg/25 mg/15 mg.	Do.
89–913	Triamcinolone Acetonide Ointment USP, 0.5%.	Alpharma, U.S. Pharmaceuticals Division, 333 Cassell Dr., suite 3500, Baltimore, MD 21224.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 23, 1999.

Dated: September 8, 1999.

Janet Woodcock

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–24720 Filed 9–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Workshop on Standards for Inactivation and Clearance of Infectious Agents in the Manufacture of Plasma Derivatives from Nonhuman Sources for Human Injectable Use; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Standards for Inactivation and Clearance of Infectious Agents in the Manufacture of Plasma Derivatives from Nonhuman Sources for Human Injectable Use.'' The purpose of the public workshop is to discuss whether infectious agent inactivation and clearance steps should become standard industry practice in the manufacture of human injectable products from nonhuman source plasma.

Date and Time: The public workshop will be held on Monday, October 25, 1999, from 9 a.m. to 3:30 p.m.

Location: The public workshop will be held at the National Institutes of Health (NIH), NIH Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

Contact:

For information regarding the public workshop and registration: Therese Burke, Laurel Consulting Group, 1815 Fort Meyer Dr., suite 300, Arlington, VA 22209, 703–351–7676, FAX 703–528–0716, e-mail: tburke@lcgnet.com.

For information regarding this document: Nathaniel L. Geary, Center for Biologics Evaluation and Research (CBER) (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210, FAX 301–594–1944.

SUPPLEMENTARY INFORMATION:

FDA is considering the requirement of inclusion of steps for the inactivation and clearance of infectious agents in the manufacture of products from nonhuman source plasma. This is an effort to level the regulatory requirements for all plasma derivatives regardless of their source and to continue to ensure high levels of safety for injectable blood products.

Many plasma derivatives represent product lines that are of critical use to a limited number of patients. Some of these products are used chronically, some acutely. For those products that utilize human plasma as a raw material, standards have been set that require inactivation procedures to be included in the manufacturing process. The risk of plasma derivatives manufactured from nonhuman raw materials has been more difficult to define. With the development of gene therapy, somatic cell therapy, and xenotransplantation, concerns are growing regarding the effect of xenobiotics on patients. Concerns have also been expressed about the use of plasma derivatives manufactured from nonhuman source plasma.

In an effort to address the needs of patients to have safe and effective blood products and to set realistic requirements for blood derivative manufacturers, FDA is sponsoring a public workshop to discuss these issues. Specifically, blood products manufactured from equine (horse), lapine (rabbit), ovine (sheep), caprine (goat), and porcine (pig) plasma and formulated into injectable products will be discussed.

Registration: Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Therese Burke (address above) by Friday, October 8, 1999. Onsite registration will be done on a space available basis on the day of the public workshop, beginning at 7:30 a.m. There is no registration fee for the public workshop. Space is limited, therefore, interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Therese Burke at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The meeting transcript will be available on CBER's website at ''http://www.fda.gov/cber/minutes/workshop-min.htm''.

Dated: September 16, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–24721 Filed 9–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request the NIH Consultant Information File System

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Center for Scientific Review (CSR), National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 24, 1999, page 28001 (Volume 64, Number 99) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, and information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: The NIH Consultant Information File System.

Type of Information Collection Request: Extension.

Form Number: OMB 0925–0358 (expiration 10/31/99) NIH 2668–1; 2668–3.

Need and Use of Information Collection: This system directly supports the recruitment and appointment of scientific experts. These experts provide evaluative advice on the merit and program relevance of the research grant applications and research contract proposals submitted to the NIH. The primary objective of this system is to support the NIH Peer Review system, but other PHS review administrative staff use the system to identify experts to support their advisory committees.

Frequency of Response: Intake established record on file, candidate can