Dated: September 19, 2000.

Nancy Cheal,

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

[FR Doc. 00–24531 Filed 9–22–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–72–00]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Exposure to Aerosolized Brevetoxins During Red Tide Events—New—National Center for Environmental Health (NCEH). *Gymnodinium breve* is the marine dinoflagellate responsible for extensive blooms (called red tides) that form in the Gulf of Mexico. G. *breve* produces potent toxins, called brevetoxins, that have been responsible for killing millions of fish and other marine organisms. The biochemical activity of brevetoxins is not completely understood and there is very little information regarding human health effects from environmental exposures, such as inhaling brevetoxin that has been aerosolized and swept onto the coast by offshore winds. The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC) is planning to recruit 100 people who work along the coast of Florida and who potentially will be occupationally exposed to aerosolized red tide toxins some time during the year following recruitment.

NCEH plans on administering a base line respiratory health questionnaire and conducting pre- and post-shift pulmonary function tests during a time when there is no red tide reported near the area. When a red tide develops, we plan to administer a symptom survey and conduct pulmonary function testing (PFT) on a group of study participants who are working in the area where the red tide is near shore, and on a control group of study participants who are not working in an area where the red tide is near shore (*i.e.*, are not exposed to the red tide). We will then compare (1) symptom reports before and during the red tide and (2) the changes in baseline PFT values during the work shift (differences between pre- and post-shift PFT results without exposure to red tide) with the changes in PFT values during the work shift when individuals are exposed to red tide. In addition, we plan to assist in collecting biological specimens (inflammatory cells from nose and throat swabs) to assess whether they can be used to verify exposure and to demonstrate a biological effect (*i.e.,* inflammatory response) from exposure to red tide. There are no costs to respondents. The total burden is estimated to be 201 hours.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Pulmonary History Questionnaire	100	1	20/60
Symptom Questionnaire	100	20	5/60

Dated: September 19, 2000.

Nancy Cheal,

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

[FR Doc. 00–24530 Filed 9–22–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Advisory Committee on Immunization Practices (ACIP) Teleconference.

Time and Date: 3:15 p.m.–5 p.m., September 28, 2000.

Place: Teleconference call will originate at the Centers for Disease Control and Prevention in Atlanta, Georgia. Please see ''Supplementary Information'' for details on accessing the teleconference.

Status: Open to the public, teleconference access limited only by availability of telephone ports.

Purpose: The Committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. § 1396s, the Committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters to be Discussed: The teleconference agenda will include a discussion of influenza vaccine recommendations for the 2000–2001 influenza season. Discussion will include priority groups for vaccination, implementation measures, and strategies for promoting vaccine delivery later in the influenza season.

Agenda items are subject to change as priorities dictate.

SUPPLEMENTARY INFORMATION: This conference call is scheduled for 3:15 p.m. Eastern Standard Time. To access the teleconference you must dial 1/888/381–5770 and enter conference code 53651. You will then be automatically connected to the call. It is necessary to meet on an expedited basis, to refine vaccine recommendations prior to the influenza season. Therefore, notice is published less than 15 days prior to the teleconference.

CONTACT PERSON FOR MORE INFORMATION: Gloria A. Kovach, Program Analyst, Epidemiology and Surveillance Division, National Immunization Program, CDC, 1600 Clifton Road, NE, m/s E61, Atlanta, Georgia 30333. Telephone 404/639–8096. 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 the

Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 20, 2000.

Carolyn J. Russell,

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

[FR Doc. 00–24622 Filed 9–22–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1502]

Agency Information Collection Activities: Proposed Collection; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

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 information collection requirements relating to FDA's adverse experience reporting (AER) for licensed biological products, and general records associated with the manufacture and distribution of biological products.

DATES: Submit written or electronic comments on the collection of information by November 24, 2000.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at: http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All documents 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: 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 request 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: (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.

Adverse Experience Reporting for Licensed Biological Products; and General Records—21 CFR 600.12 and Part 600 Subpart D (OMB Control Number 0910–0308)—Extension

Under the Public Health Service Act (42 U.S.C. 262), FDA is required to ensure the marketing of only those biological products which are safe and effective. FDA must therefore be informed of all adverse experiences occasioned by the use of licensed biological products. FDA issued the adverse experience reporting requirements to enable FDA to take actions necessary for the protection of the public health in response to reports of adverse experiences related to licensed biological products. The primary purpose of FDA's adverse experience reporting system is to flag potentially serious safety problems with licensed biological products, focusing especially on newly licensed products. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the licensed biological product provides the opportunity to collect information on rare, latent, and long-term effects. Reports are obtained from a variety of sources, including patients, physicians, foreign regulatory agencies, and clinical investigators. Information derived from the adverse experience reporting system contributes directly to increased public health protection because such information enables FDA to recommend important changes to the product's labeling (such as adding a new warning), to initiate removal of a biological product from the market when necessary, and to assure the manufacturer has taken adequate corrective action if necessary.

Section 600.80(c)(1) (21 CFR 600.80(c)(1)), requires the licensed manufacturer to report each adverse experience that is both serious and unexpected, regardless of source, as soon as possible but in any case within 15 working days of initial receipt of the information. Section 600.80(e) requires licensed manufacturers to submit a 15-day alert report obtained from a postmarketing clinical study only if there is a reasonable possibility that the product caused the adverse experience. Section 600.80(c)(2) requires the licensed manufacturer to report each adverse experience not reported under paragraph (c)(1) at quarterly intervals, for 3 years from the date of issuance of the product license, and then at annual intervals. The majority of the periodic reports will be submitted annually since a large percentage of the current licensed biological products have been licensed longer than 3 years. Section 600.80(i) requires the licensed manufacturer to maintain for a period of 10 years records of all adverse experiences known to the licensed manufacturer, including raw data and any correspondence relating to the adverse experiences. Section 600.81 (21 CFR 600.81) requires the licensed manufacturer to submit information about the quantity of the product distributed under the product license, including the quantity distributed to distributors at an interval of every 6 months. The semiannual distribution report informs FDA of the quantity, the lot number, and the dosage of different products. Section 600.90 (21 CFR