reducing barriers that result in low immunization coverage for children.

Matters to be Discussed: Agenda items will include an update on publication of the newly revised Adult and Pediatric Immunization Standards; a discussion of adolescent immunization; Immunization Registries—Updates on the use of VFC funds for registry development standards of excellence; PCV7 update on impact of shortage on coverage and active bacterial core surveillance; a discussion of the draft report from the Workgroup on Public Health Options for Implementing Immunization Recommendations; updates on pneumococcal and influenza coverage; and a review of data on the burden of pneumococcal disease.

Name: Subcommittee on Vaccine Safety and Communication.

Time and Date: 2:30 p.m.–5 p.m., June 3, 2003.

Place: Hubert H. Humphrey Building, Room 425A, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Purpose: This subcommittee reviews issues relevant to vaccine safety and adverse reactions to vaccines.

Matters to be Discussed: Next Steps in Risk Communication: Reviews of IOM Immunization Safety Review Committee Recommendations, and of NVPO Workshop Recommendations; a discussion of the influenza communications programs; a discussion of next topics for the IOM Safety Review Committee; a review of the National Immunization Program Website; and, an update on thimerosal-related litigation.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Gloria Sagar, Committee Management Specialist, NVPO, CDC, 4700 Buford Highway M/S K–77, Chamblee, Georgia 30341, telephone 770/488–2040.

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

Dated: May 7, 2003.

Alvin Hall,

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

[FR Doc. 03–11877 Filed 5–12–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0449]

Agency Information Collection Activities; Announcement of OMB Approval; Revisions to the General Safety Requirements for Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Revisions to the General Safety Requirements for Biological Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of March 4, 2003 (68 FR 10157), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0504. The approval expires on April 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: May 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11772 Filed 5–12–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0034]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; FDA Safety Alert/Public Health Advisory Readership Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the information collection by June 12, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

FDA Safety Alert/Public Health Advisory Readership Survey (OMB Control Number 0910–0341)—Extension

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 375(b)) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH) communicates these risks to user communities through two publications: (1) The FDA Safety Alert and (2) the Public Health Advisory. Safety alerts and advisories are sent to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers. Subjects of previous alerts included spontaneous combustion risks in large quantities of patient examination gloves, hazards associated with the use of electric heating pads, and retinal photic injuries from operating microscopes during cataract surgery.

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. FDA seeks to evaluate the clarity, timeliness, and impact of safety alerts

and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address how clearly actions for reducing risk are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risk as a result of information in the alert. Subjects will also be asked whether they wish to receive future alerts electronically, as well as how the safety alert program might be improved.

The information collected will be used to shape FDA's editorial policy for the safety alerts and public health advisories. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content, format, and method of dissemination.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Hours
308	3	924	.17	157

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

Based on the history of the safety alert and public health advisory program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey and through discussions with the contacts in trade organizations.

Dated: May 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11773 Filed 5–12–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0224]

Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance (#118) entitled ''Guidance For Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues.'' This guidance describes the basic principles the agency recommends for development, evaluation, or application of qualitative mass spectrometric methods for confirming the identity of new animal drug residues. This guidance document is intended for technical professionals familiar with mass spectrometry. A glossary at the end of the guidance defines key terms used throughout the document.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Once on this site, select ''Docket No. 01D–0224 Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues'' and follow the directions. Comments should be identified with the full title of the guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: David N. Heller, Center for Veterinary Medicine (HFV–510), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301–827–8156, e-mail: dheller@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 13, 2001 (66 FR 31938), FDA published a notice of availability for a draft guidance entitled ''Draft Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues'' giving interested persons until September 11, 2001, to submit comments. FDA considered all comments received and, where appropriate, incorporated them into the guidance. The guidance differs from the draft guidance in the following ways:

- There is further clarification of interference testing, control samples, system suitability, minimum signal strength in full scan analysis, recommended rate of false negatives, and number of residue-incurred samples for validation. (The recommendation in the 1994 revision of CVM Guidance #3 for a smaller number of incurred samples for interlaboratory method trials has not been CVM's practice for some years. CVM is currently revising Guidance #3.)
- Additional definitions were provided for comparison standard, control sample exact mass measurement, false positive rate, false negative rate, limit of confirmation, and validation. Other revisions in the glossary definitions were made to make the definitions consistent with definitions in existing regulations.
- Use of the terms ''acceptability range'' and ''precursor ion'' is now consistent.
- General recommendations on the subject of exact mass measurements have been added. Until specific standards for exact mass measurements in animal drug residue analysis are generally accepted, their use will be evaluated on a case-by-case basis. The Center for Veterinary Medicine (CVM) of FDA may modify this document if a more generally accepted standard for confirmation of animal drug residues using exact mass measurements is developed in the future.

The purpose of this guidance document is to facilitate and expedite coordination between CVM and sponsors so the development, evaluation, and application of qualitative mass spectrometric methods will be completed in a consistent and timely manner. This guidance document is intended for technical professionals familiar with mass spectrometry. A glossary at the end of the guidance defines key terms used throughout the document.

This guidance should be used: (1) In the development of new methods, (2) the review of methods submitted to