will be added in years 2 and 3, depending on funding.

CDC is requesting a three-year OMB clearance of collecting the NEDSS data that is not currently covered by existing clearances. There are no costs to respondents other than their time. The average total annualized burden for the Weekly Morbidity Reports and the Annual Summary Report is 660 hours.

ANNUALIZED WEEKLY MORBIDITY REPORT RESPONDENT BURDEN

Type of respondent	Number of respondents	Number of responses per respondents	Average burden per response (in hours)
States	20	52	30/60

ANNUALIZED ANNUAL SUMMARY REPORT RESPONDENT BURDEN

Type of respondent	Number of respondents	Number of responses per respondents	Average burden per response (in hours)
States	20	1	7

Dated: April 28, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–7077 Filed 5–9–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety and Defense Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Regional Small Business Representative (SWR SBR) Program, in collaboration with The University of Arkansas and the Mid-Continental Association of Food and Drug Officials, is announcing a public workshop entitled ''Food Safety and Defense Workshop.'' This public workshop is intended to provide information about current Good Manufacturing Practice regulations for foods, Hazard Analysis Critical Control Point (HACCP), food defense awareness, and other related subjects to the regulated industry, particularly small businesses and startups.

Date and Time: This public workshop will be held on June 6 and 7, 2006, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Continuing Education Center in Fayetteville, AR, located downtown (2 East Center St.).

Accommodations: There are many lodging choices in the area, but the Radisson Hotel in Fayetteville (479–442–5555) is immediately adjacent to the Continuing Education Center.

Contact: Steven C. Seideman, 2650 North Young Ave., Institute of Food Science & Engineering, University of Arkansas, Fayetteville, AR 72704, 479–575–4221, FAX: 479–575–2165, or e-mail: *seideman@uark.edu*.

You may also contact David Arvelo, Food and Drug Administration, 4040 N Central Expressway, suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, or e-mail: *david.arvelo@fda.hhs.gov*.

Registration: Registration by May 28, 2006, is encouraged. The University of Arkansas has a $150 registration fee to cover the cost of facilities, materials, speakers, and breaks. Please submit your registration as soon as possible. Those accepted into the course will receive confirmation. Registration at the site is not guaranteed, but may be possible on a space-available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is $200, payable to ''The University of Arkansas.'' If you need special accommodations due to a disability, please contact Steven C. Seideman (see *Contact*) at least 7 days in advance.

Registration Form Instructions: To register, please complete the form available online at *http://www.mcafdo.org/* or the registration form in this document and submit along with a check or money order for $150 payable to the ''The University of Arkansas.'' Mail to: Institute of Food Science & Engineering, University of Arkansas, 2650 North Young Ave., Fayetteville, AR 72704.

FOOD SAFETY AND DEFENSE WORKSHOP REGISTRATION FORM

Name:

Affiliation:

Mailing Address:

City/State/Zip Code:

Phone:

FOOD SAFETY AND DEFENSE WORKSHOP REGISTRATION FORM—Continued

Fax:

E-mail:

Special Accommodations Required:

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested at cost through the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: This public workshop is being held in response to the large volume of food safety and defense inquiries from small food manufacturers and startups originating from the area covered by the FDA Dallas District Office. The SWR SBR presents these workshops to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the Small Business Representative Program, which are in part to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as outreach activities by Government agencies to small businesses.

The goal of this public workshop is to present information that will enable manufacturers and regulated industry to better understand food safety and defense requirements and guidance, especially in light of growing concerns about food safety, food allergen cross-contact, and food defense. Information presented will be based on agency position as articulated through regulation, compliance policy guides, and information previously made available to the public. The following topics will be discussed at the workshop: (1) Code of Federal Regulations, Title 21, Part 110, *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food*, (2) pathogens of public health concern, (3) food allergen cross-contact, (4) an overview of HACCP, and (5) food defense awareness; as well as other related topics. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the regulatory and policy perspectives on food safety and defense and will increase voluntary compliance.

Dated: May 4, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–4366 Filed 5–5–06; 3:27 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0172]

Draft Guidance for Clinical Investigators, Institutional Review Boards, and Sponsors; Process for Handling Pediatric Referrals to the Food and Drug Administration: Additional Safeguards for Children in Clinical Investigations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry; Process for Handling Pediatric Referrals to FDA: Additional Safeguards for Children in Clinical Investigations.'' This guidance is intended to assist clinical investigators, institutional review boards (IRBs), sponsors, and other interested parties in understanding FDA's process for handling clinical investigations that include children as subjects and that have been referred to FDA for review under FDA regulations on additional safeguards for children in clinical investigations. The draft guidance describes the procedures FDA generally intends to follow in handling clinical investigations referred for review under these regulations and in reaching final determinations in accordance with these regulations.

DATES: Submit written or electronic comments on the draft guidance by July 10, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800–835–4709 or 301–827–1800.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry; Process for Handling Referrals to FDA Under 21 CFR 50.54: Additional Safeguards for Children in Clinical Investigations.'' FDA issued 21 CFR part 50, subpart D, ''Additional Safeguards for Children in Clinical Investigations,'' (part 50, subpart D) as an interim final rule on April 24, 2001 (66 FR 20598). Under these regulations, an IRB must review clinical investigations involving children as subjects and covered by subpart D and approve only those clinical investigations that satisfy the criteria described in §§ 50.51, 50.52, or 50.53, as well as the conditions of all other applicable sections in subpart D.

Under § 50.54, if an IRB does not believe that a clinical investigation within the scope described in §§ 50.1 and 56.101 (21 CFR 56.101) and involving children as subjects meets the