

there was a red tide and then examined the data to see if red tide exposure had an effect on symptom reports or PFT results.

NCEH requests a revision of data collection procedures for the currently approved project and an additional three year extension. Unfortunately, the exposures experienced by the study cohort have been minimal, and NCEH

plans to conduct another study (using the same symptom surveys and PFTs) during a more severe red tide event. First, NCEH wants to quantify the levels of cytokines in nasal exudates to assess whether they can be used to verify exposure and to demonstrate a biological effect (i.e., allergic response) following inhalation of aerosolized brevetoxins. NCEH will collect nasal

exudates at the same time the PFTs are done.

NCEH plans to include the study subjects who have been involved in the earlier studies and any new individuals (n=25) who have been hired to work at the relevant beaches.

There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Instrument type	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Pulmonary History Survey .....	10	1	20/60	3
Symptom survey .....	25	6	5/60	13
Total .....				16

**Catina Conner,**  
Assistant Reports Clearance Officer, Centers for Disease Control and Prevention.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Ethics Subcommittee, Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC); Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention announce the following Subcommittee meeting.

*Name:* Ethics Subcommittee, Advisory Committee to the Director.

*Time and Date:* 12 p.m.-1:30 p.m., EDT, Thursday, September 25, 2008.

*Place:* This meeting will be held by conference call. The call in number is (866) 919-3560 and entering code 4168828.

*Status:* Open to the public. The public is welcome to comment during the public comment period which is tentatively scheduled from 1 p.m.-1:15 p.m.

*Purpose:* The Ethics Subcommittee will provide counsel to the ACD, CDC regarding a broad range of public health ethics questions and issues arising from programs, scientists and practitioners.

*Matters To Be Discussed:* Agenda items will include review of ethics guidance for public health emergency preparedness and response.

*For Further Information Contact:* For more information about this meeting contact Drue Barrett, PhD., Designated Federal Official, Ethics Subcommittee, CDC, 1600 Clifton Road, NE., M/S D-50, Atlanta, Georgia

30333, Telephone (404)639-4690, e-mail: dbarrett@cdc.gov.

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 4, 2008.

**Elaine L. Baker,**  
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-N-0239]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring**

**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 review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by October 10, 2008.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0409. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3792.

**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.

**Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring (OMB Control Number 0910-0409)—Extension**

FDA is requesting OMB approval of the information collection requirements contained in 21 CFR 315.4, 315.5, and 315.6. These regulations require manufacturers of diagnostic radiopharmaceuticals to submit information that demonstrates the safety and effectiveness of a new diagnostic radiopharmaceutical or of a new indication for use of an approved diagnostic radiopharmaceutical.

In response to the requirements of section 122 of the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), FDA published a final rule in the **Federal**