

CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 27, 2012.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *Live Oak Bancshares, Inc.*, Wilmington, North Carolina; to engage *de novo* through its subsidiary, BANKR, LLC, Wilmington, North Carolina, in data processing activities, pursuant to section 225.28(b)(14)(i) of Regulation Y.

B. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Waytru Bancorp.*, Cambridge City, Indiana; to continue to engage in extending credit and servicing loans, pursuant to section 225.28(b)(1) of Regulation Y.

Dated: Board of Governors of the Federal Reserve System, February 7, 2012.

**Jennifer J. Johnson**,  
Secretary of the Board.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the National Biodefense Science Board

**AGENCY:** Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the

National Biodefense Science Board (NBSB) will be holding a closed session by teleconference under exemption 9(B) of the Government in Sunshine Act, 5 U.S.C. 552b(c).

**DATES:** The February 28, 2012 NBSB closed session by teleconference is tentatively scheduled from 9 a.m. to 1 p.m. The agenda and time is subject to change as priorities dictate.

**ADDRESSES:** The closed session will occur by teleconference and will not be open to the public as stipulated under exemption 9(B) of the Government in Sunshine Act, 5 U.S.C. 552b(c).

**FOR FURTHER INFORMATION CONTACT:** MacKenzie Robertson, Acting Executive Director, NBSB, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services; 202-260-0447; fax 202-205-8508; Email: [NBSB@HHS.GOV](mailto:NBSB@HHS.GOV).

**SUPPLEMENTARY INFORMATION:** Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d-7f) and section 222 of the Public Health Service Act (42 U.S.C. 217a), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary and/or the Assistant Secretary for Preparedness and Response on other matters related to public health emergency preparedness and response.

**Background:** The Board is being asked to review and evaluate the 2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP). Until a final document is approved by the Secretary of the Department of Health and Human Services (HHS), the development of PHEMCE SIP requires consideration and discussion of procurement-sensitive information that should not be released to the public prior to the Secretary's final decision. Premature public disclosure of the draft PHEMCE SIP would limit the Secretary's decision-making ability to effectively prioritize HHS expenditures on critical medical countermeasures. Therefore, the Board's deliberations on the new task will be conducted in closed session in accordance with provisions set forth under exemption 9(B) of the Government in Sunshine Act, 5 U.S.C. section 552b(c), and with

approval by the Assistant Secretary for Preparedness and Response.

**Availability of Materials:** The meeting materials will be posted on the NBSB Web site at [www.phe.gov/nbsb](http://www.phe.gov/nbsb).

**Procedures for Providing Public Input:** All written comments should be sent by email to [NBSB@HHS.GOV](mailto:NBSB@HHS.GOV) with "NBSB Public Comment" as the subject line.

Dated: February 6, 2012.

**Nicole Lurie**,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2012-3127 Filed 2-9-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Member Conflict Review, Program Announcement (PA) 07-318, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

**Time and Date:** 1 p.m.-3 p.m., March 7, 2012 (Closed).

**Place:** National Institute for Occupational Safety and Health (NIOSH), CDC, 1095 Willowdale Road Morgantown, West Virginia 26506, Telephone: (304) 285-6143.

**Status:** The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

**Matters To Be Discussed:** The meeting will include the initial review, discussion, and evaluation of applications received in response to "Member Conflict Review, PA 07-318."

**Contact Person for More Information:** Bernadine Kuchinski, Ph.D., Scientific Review Administrator, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, Robert A. Taft Laboratories, 4676 Columbia Pkwy, MS C-7, Cincinnati, Ohio 45226; Telephone: (513) 533-8511.

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: February 6, 2012.

**Elaine L. Baker,**

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

[FR Doc. 2012-3114 Filed 2-9-12; 8:45 am]

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0793]

**Agency Information Collection  
Activities; Submission for Office of  
Management and Budget Review;  
Comment Request; Medical Device  
Recall Authority**

**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 March 12, 2012.

**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: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the

OMB control number 0910-0432. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**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.

**Medical Device Recall Authority—21 CFR Part 810 (OMB Control Number 0910-0432)—Extension**

This collection of information implements section 518(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360h(e)) and part 810 (21 CFR part 810), medical device recall authority provisions. Section 518(e) of the FD&C Act provides FDA with the authority to issue an order requiring an appropriate person, including manufacturers, importers, distributors, and retailers of a device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death, to: (1) Immediately cease distribution of such device, (2) immediately notify health professionals and device-user facilities of the order, and (3) instruct such professionals and facilities to cease use of such device.

Further, the provisions under section 518(e) of the FD&C Act set out the following three-step procedure for

issuance of a mandatory device recall order:

1. If there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may issue a cease distribution and notification order requiring the appropriate person to immediately:

- Cease distribution of the device,
- Notify health professionals and device user facilities of the order, and
- Instruct those professionals and facilities to cease use of the device;

2. FDA will provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be modified, vacated, or amended to require a mandatory recall of the device; and

3. After providing the opportunity for an informal hearing, FDA may issue a mandatory recall order if the Agency determines that such an order is necessary.

The information collected under the recall authority provisions will be used by FDA to do the following: (1) Ensure that all devices entering the market are safe and effective, (2) accurately and immediately detect serious problems with medical devices, and (3) remove dangerous and defective devices from the market.

In the **Federal Register** of November 16, 2011 (76 FR 71041), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
810.10(d) .....	2	1	2	8	16
810.11(a) .....	1	1	1	8	8
810.12(a) and (b) .....	1	1	1	8	8
810.14 .....	2	1	2	16	32
810.15(a), (b), and (c) .....	2	1	2	12	24
810.15(d) .....	2	1	2	4	8
810.15(e) .....	10	1	10	1	10
810.16(a) and (b) .....	2	12	24	40	960
810.17(a) .....	2	1	2	8	16
<b>Total Hours</b> .....					<b>1,082</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.