presentations should be limited to 15 minutes.

The purpose of the meeting is to obtain comments from individuals regarding potential chemical and biological respiratory protection standards and guidelines that NIOSH is developing in collaboration with SBCCOM and NIST.

After reviewing the requests for presentations, NIOSH will notify each presenter by mail or telephone of the approximate time that his or her oral presentation is scheduled to begin. If a participant is not present when his or her presentation is scheduled to begin, the remaining participants will be heard in order. At the conclusion of the meeting, an attempt will be made to allow presentations by any scheduled participants who missed their assigned times. Attendees who wish to speak but did not submit a request for the opportunity to make presentations may be given this opportunity at the conclusion of the meeting, at the discretion of the presiding officer.

SUMMARY: The Agencies will provide information to attendees concerning the progress of their collaborative efforts and their current understanding of chemical, biological, and radiological respiratory protection issues including threats or hazards, and the developmental status of chemical and biological standards and guidelines. Participants will be given an opportunity to ask questions of Agencies' representatives, and to present individual comments that they wish to have considered.

Background

Due to the recognition that terrorism is a national domestic security issue, municipal, state, and national guard responder groups, particularly those in locations considered potential targets, have been developing response and consequence management plans. The federal Interagency Board for Equipment Standardization and Interoperability (IAB) has worked to identify personal protective equipment that is already available on the market for responders' use. The IAB has identified the development of standards or guidelines for respiratory protection equipment as a top priority. NIOSH, NIST, National Fire Protection Association and the Occupational Safety and Health Administration have entered into a Memorandum of Understanding defining each agency or organization's role in developing, establishing and enforcing standards or guidelines for responders' respiratory protective devices. NIST has initiated Interagency Agreements with NIOSH and SBCCOM to aid in the development of appropriate respiratory protection standards or guidelines. NIOSH has the lead in developing standards or guidelines to test, evaluate and approve respirators.

Specific Discussion and Comment Topics

NIOSH, SBCCOM, and NIST are holding this meeting to present their progress in assessing respiratory protection needs of responders to chemical, biological, and radiological incidents. The Agencies will present their methods or models for developing hazard and exposure estimates, and their status in evaluating test methods and performance standards that may be applicable as future chemical and biological respirator standards or guidelines. Participants are invited to provide their individual comments on these topics and to identify additional information that will help in developing respiratory standards and guidelines.

The Agencies have evaluated threat and vulnerability assessments and other associated documents to gain understanding of probable terrorism agents including chemical warfare agents, biological warfare agents, and toxic industrial materials. A summary of the findings will be presented at the meeting for discussion and comment by the attendees.

There are multiple classes of respirators having various operational parameters. The Agencies are currently aware that the domestic preparedness community is purchasing self-contained breathing apparatus (SCBA), and full facepiece powered and non-powered air-purifying respirators to equip response teams for which there are no NIOSH chemical/biological respirator approval standards. NIOSH and SBCCOM are in the process of developing chemical and biological respiratory protection standards and guidelines, and will present pertinent information for each class of respirator. The Agencies will discuss potential tests and test parameters being considered for each respirator class.

For SCBA, the parameters are system and component agent permeation testing and laboratory protection level testing. For air-purifying respirators, the same parameters are being considered plus challenge concentrations, breakthrough and end-point concentrations, breathing flow rates, hot and cold temperature function, human wear factors, assessment of current respirator technologies, etc. The status of NIOSH and SBCCOM in these efforts will be presented at the meeting. Participants are invited to provide individual comment on these and other performance, quality, or operational parameters that should be considered.

Comments on the topics presented in this notice should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513–533–8450, fax 513/533–8230. Comments may also be submitted by e-mail to: NIOCINDOCKET@CDC.GOV. E-mail attachments should be formatted as WordPerfect 6/7/8/9, or Microsoft Word. Comments should be submitted to NIOSH no later than May 31, 2001, and should reference docket number, NIOSH–002, in the subject heading.

FOR FURTHER INFORMATION CONTACT: John M. Dower or Ray Wells, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505–2888, telephone 304/285–5907, fax 304/285–6030 and/or Email: respcert@cdc.gov. or Mr. Wayne Davis, Product Director for Respiratory Protection, Project Manager for Nuclear, Biological and Chemical Defense Systems, SBCCOM, 5183 Blackhawk Road, Aberdeen Proving Ground, MD 21010–5424, ATTN: AMSSB–PM–RNN–P/ Mr. Wayne Davis, telephone 410 436–1776, fax 410 436–4185 and/or *Wayne.davis@sbccom.apgea.army.mil.*

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: March 15, 2001.

John Burckhardt,

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

[FR Doc. 01–6977 Filed 3–20–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0086]

Draft Guidance for Industry: Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research'' dated February 2001. This document, when finalized, is intended to provide guidance to sponsors of applications that are the subject of an open advisory committee meeting convened by the Center for Biologics Evaluation and Research (CBER), beginning on June 1, 2001. The draft guidance document provides procedures that will be adopted by CBER for making information provided to advisory committee members in connection with such meetings publicly available. The draft guidance document also describes how a sponsor should prepare its submission to an advisory committee.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by May 21, 2001. General comments on agency guidance documents are welcome at any time. Submit written comments on the collection of information by May 21, 2001.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self–addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document and on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research'' dated February 2001. This draft guidance document, when finalized, is intended to provide guidance to sponsors of applications that are the subject of an open advisory committee meeting convened by CBER, beginning on June 1, 2001. The draft guidance document describes procedures that will be adopted by CBER for making information that is provided to advisory committee members in connection with such meetings publicly available. The draft guidance also describes how a sponsor should prepare its submission to an advisory committee.

In the **Federal Register** of November 30, 1999 (64 FR 66920), FDA issued a notice announcing the availability of a guidance document entitled ''Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000'' (the disclosure policy guidance). The disclosure policy guidance provided FDA's interpretation of the Federal Advisory Committee Act (the FACA, 5 U.S.C. app. 2) and § 314.430 (21 CFR 314.430) with respect to the disclosure of materials provided to advisory committees, and how FDA will exercise its discretion under § 314.430(d)(1) in connection with open advisory committee meetings convened by the Center for Drug Evaluation and Research (CDER), beginning on January 1, 2000. In the **Federal Register** of December 22, 1999 (64 FR 71794), FDA announced the availability of a draft guidance document entitled ''Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000.'' That draft guidance document was intended to provide the procedural information referenced in the disclosure policy guidance. Consistent with these principles and the regulations governing disclosure of information concerning biologic license applications at § 601.51 (21 CFR 601.51), CBER is providing this draft guidance on what sponsors may expect concerning the disclosure of information related to an open advisory committee meeting. As stated in the draft guidance, FDA interprets § 601.51 to be consistent with the FACA, and therefore, will exercise its discretion under § 601.51(d)(1) in a manner consistent with FACA and the Freedom of Information Act (the FOIA) (5 U.S.C. 552) to make available for public inspection and copying materials provided to members of an advisory committee in connection with open advisory committee meetings related to the testing or approval of biologic products and convened by CBER, beginning on June 1, 2001.

The draft guidance document entitled ''Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research'' being announced in this notice is intended to be consistent with CDER's current guidance procedures where possible, and to describe procedures in making the process of complying with the disclosure requirements of the FACA as efficient as possible. These procedures address: (1) The content and organization of a sponsor submission for an advisory committee; (2) the timing of the sponsor submission to CBER; and (3) the process by which CBER will review and redact the sponsor submission and the related CBER submission. However, FDA may revise the draft CBER and CDER guidances based on comments received.

This draft guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document represents the agency's current thinking on the implementation by CBER of the disclosure provisions of the FACA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 requests 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 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.

Draft Guidance for Industry on Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research

FDA is issuing a draft guidance document on procedures that will be adopted by CBER for making information that is provided to advisory committee members in connection with open advisory committee meetings publicly available. The procedures address: (1) The content and organization of a sponsor submission for an advisory committee, (2) the timing of the sponsor submission to CBER, and (3) the process by which CBER will review and redact the sponsor submission and the related CBER submission. Under existing regulations in 21 CFR 14.35(a), sponsors routinely submit information to the agency that will be provided to advisory committee members in connection with advisory committee meetings. A sponsor may submit a package that the sponsor states should be fully disclosed to the public or a package that contains information the sponsor asserts should be withheld from public disclosure under the FOIA. This draft guidance describes the submission of information to the agency that will be provided to the members of an advisory committee in connection with an open advisory committee meeting related to the testing or approval of a biologic product and convened by CBER, beginning on June 1, 2001.

FDA construes the FACA to require that, with respect to any open advisory committee meeting convened under the FACA, whenever practicable and subject to any applicable exemption of the FOIA, those materials that are provided to the members of a CBER advisory committee in connection with that meeting must be made available for public inspection and copying before or at the time of the advisory committee meeting. Therefore, under the draft guidance document, a sponsor may submit two types of packages of materials for an advisory committee in connection with an open advisory committee meeting convened by CBER as follows: (1) A package that the sponsor states should be fully disclosed to the public because it does not contain information that should be withheld from public disclosure under an exemption under the FOIA; or (2) a package that contains information the sponsor asserts should be withheld from public disclosure under the FOIA and that, therefore, must be reviewed by the agency's Freedom of Information staff to ensure that the appropriate information is redacted. The procedures for submitting the two collections of information are described in the draft guidance document.

A. Fully Releasable Submissions

In the draft guidance document, sponsors are strongly encouraged to submit advisory committee packages that may be publicly disclosed in their entirety (i.e., that do not contain any information that the sponsor wishes to assert is exempt from disclosure under the FOIA because it is trade secret or confidential commercial information, or because it is information the disclosure of which would constitute an unwarranted invasion of personal privacy, for example, by clearly identifying individual subjects). Sponsors are also encouraged to submit an electronic version of the package.

B. Submissions That Contain Material the Sponsor Asserts Are Exempt From Disclosure

A sponsor may believe that it is necessary to include material in an advisory committee package that it believes is exempt from disclosure. As described in the guidance, the agency recommends in this circumstance that the sponsor segregate the material it believes is exempt from disclosure from the disclosable material, clearly designate the material that the sponsor believes is exempt from disclosure, and provide a detailed justification of both why that specific information is necessary for the advisory committee's consideration and why it is exempt from disclosure. Sponsors are also encouraged to submit an electronic version of the package.

1. Description of Respondents

A sponsor of an unapproved biological license application (BLA), BLA supplement, or a sponsor of an unapproved new drug application (NDA), NDA supplement, or abbreviated new drug application (ANDA) reviewed by CBER, or device (to the extent permitted by law and if the device application is being discussed in unison with a BLA) that is the subject of an open advisory committee convened by CBER, beginning on June 1, 2001.

2. Burden Estimate

Table 1 of this document provides an estimate of the annual reporting burden for the submission under the guidance of information to CBER that will be provided to the members of an advisory committee in connection with an open advisory committee meeting related to the testing or approval of a biologic product and convened by CBER, beginning on June 1, 2001.

In calendar year 2000, CBER received a total of eight submissions from six sponsors (respondents) in connection with open advisory committee meetings regarding the testing or approval of biologic products. CBER expects that annually, the number of submissions and respondents will remain approximately the same. The procedures for submitting this information that are set forth in the draft guidance document were not in place in calendar year 2000. However, based on CBER's experience with the advisory committee process, and given that the guidance document strongly encourages respondents to submit advisory committee packages that may be publicly disclosed in their entirety, CBER estimates that approximately two-thirds of the total number of respondents (i.e., four respondents) will submit packages that may be disclosed in their entirety, and that approximately two-thirds of the total number of submissions that CBER receives (i.e., five responses) will be fully releasable. In addition, CBER estimates that approximately one-third of the total number of respondents (i.e., two respondents) will submit packages that contain material that the sponsor asserts is exempt from disclosure, and that approximately one-third of the submissions that CBER receives (i.e,

three responses) will contain information that the sponsor asserts is exempt from disclosure.

Based on FDA experience and information provided to the agency by industry, FDA estimates that approximately 700 hours on average would be needed for the preparation of a fully releasable submission and 1,400 hours for that of a submission that contains information the respondent asserts is exempt from disclosure, including the time FDA expects it will take a sponsor to submit an electronic version of the package. The total estimated burden hours under the draft guidance are 7,700. FDA invites comments on the analysis of information collection burdens.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Submissions	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total hours
Fully releasable submissions	4	1.25	5	700	3,500
Submissions that contain material that is claimed to be exempt from disclosure	2	1.5	3	1,400	4,200
Total	6	.....	8	.....	7,700

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

III. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document and on the collection of information. Submit written comments to ensure adequate consideration in preparation of the final document by May 21, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: March 9, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–6937 Filed 3–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4579–FA–05]

Announcement of Funding Award—Fiscal Year 2000, Office of Healthy Homes and Lead Hazard Control, National Center for Lead Safe Housing

AGENCY: Office of Healthy Homes and Lead Hazard Control, HUD.

ACTION: Announcement of funding award.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of a funding decision made by the Department to the National Center for Lead Safe Housing. This announcement contains the name and address of the awardee and the amount of the award.

FOR FURTHER INFORMATION CONTACT: Joey Zhou, Department of Housing and Urban Development, 451, Seventh Street, SW, Washington, DC, 20410, telephone (202) 755–1785, ext. 153 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number by calling the Federal Information Relay Service TTY at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Lead Hazard Control grant for the National Center for Lead Safe Housing was issued pursuant to Pub. L. 102–550, Title X; FY 2000 budget; House Appropriations Committee Report 2684–21.

This notice announces the award of $750,000 to the National Center for Lead Safe Housing which will be used to provide funding to examine and disseminate innovative, lower cost hazard control and educational strategies and provide technical assistance for integrating lead safety in HUD programs.

The Catalog of Federal Domestic Assistance number for this program is 14.900.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545), the Department is publishing the name, address, and amount of the award as follows: National Center for Lead Safe Housing, 10227 Wincopin Circle, Suite 205, Columbia, MD 21044, Amount of Grant: $750,000.

Dated: March 13, 2001.

David E. Jacobs,

Acting Director, Office of Healthy Homes and Lead Hazard Control.

[FR Doc. 01–6933 Filed 3–20–01; 8:45 am]

BILLING CODE 4210–01–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Advisory Committee on Water Information; Notice of Reestablishment

This notice is published in accordance with section 9 (a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463), 5 U.S.C. App. (1988). Following consultation with the General Services Administration, notice is hereby given that the Secretary of the Interior is reestablishing the Advisory Committee on Water Information (ACWI). OMB Memorandum 92–01 dated December 10, 1991, designated the U.S. Geological Survey (USGS) as the lead agency for the Water Information Coordination Program (WICP) and also designated all other Federal organizations using water resources information to assist the USGS in ensuring the implementatin of an effective WICP.

The purpose of the Committee is to represent the interests of water-information users and professionals in advising the Federal Government on Federal water-information programs and their effectiveness in meeting the Nation's water-information needs. Member organizations will help to foster communications between the Federal and non-Federal sectors on sharing water information.