names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2(d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the act.

FDA estimates the burden of complying with the enforcement notification requirement as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.2(d)	5	1	5	2	10

There are no capital costs or operating and maintenance costs associated with this collection.

Based upon the small number of enforcement notifications received from the States since the enactment of section 310(b) of the act in 1990, FDA estimates that no more than five notifications will be submitted annually. Because 21 CFR 100.21(d) implements a statutory information collection requirement, only the additional burden attributable to the regulation has been included in the estimate.

4. Reference Amount Petitions (21 CFR 101.12(h)) (OMB Control Number 0910–0286—Reinstatement)

Section 403(q)(1)(A) of the act (21 U.S.C. 343(q)(1)(A)) requires that the label or labeling of food provide nutrition information that includes the serving size or, if the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food. In response to section 2(b)(1)(B) of the 1990 amendments, FDA issued regulations defining the serving size (or other unit of measure) for various types of food. Food producers are required to use the reference amount values provided in § 101.12 (21 CFR 101.12) and the rules for establishing serving sizes that are prescribed in 21 CFR 101.9(b) to determine the appropriate serving size for their products; however, a manufacturer or other interested person may submit a petition to establish or amend the reference amount value for a food or to create a new food subcategory with its own reference amount. Section 101.12(h) sets forth the information the petitioner is required to include in the petition.

FDA estimates the burden resulting from the requirements of § 101.12(h) as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
101.12(h)	5	1	5	80	400	$400,000

There are no capital costs associated with this collection.

Since the enactment of the 1990 amendments that revised the act by adding section 403(q), FDA has received nine petitions to amend existing reference amounts. Based upon these submissions, FDA estimates that no more than five such petitions will be submitted annually. The estimate for operating and maintenance costs is based on the average cost of conducting a consumer survey to support a reference amount petition.

Dated: October 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–27747 Filed 10–28–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0345]

Issues Related to Pharmaceutical Laboratory Practices Procedures; Notice of Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meetings; request for submission of topics.

SUMMARY: The Food and Drug Administration's (FDA's) Office of Regulatory Affairs (ORA) is announcing a series of meetings to be held with the pharmaceutical industry. These meetings will follow a prescribed format and will involve representatives from ORA's Division of Field Science, Field Drug laboratories, Center for Drug Evaluation and Research's (CDER's) Office of Pharmaceutical Science and other representatives from the field and headquarters. The purpose of these meetings is to continue a dialogue with trade associations, technical and professional organizations, and FDA to discuss issues of mutual concern to the agency and industry associated with pharmaceutical laboratory practices and procedures. The intent of the dialogue is to explore issues of mutual concern that affect the agency and industry laboratories.

DATES: The first meeting will be held on Wednesday, November 20, 1996, from 8:30 a.m. to 4:30 p.m. Submit topics and written comments by Friday, November 8, 1996. Interested persons may contact the information contact person (address below) for registration forms. There is no registration fee for this meeting. However, advance registration is required because space is limited.

ADDRESSES: The first meeting will be held at the Parklawn Bldg., 5600 Fishers Lane, conference room M, Rockville, MD. Submit written comments to the

Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Persons who are unable to attend, or who cannot be accommodated due to space limitations, are invited to provide written comments. A transcript of the meeting may be seen at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Elise A. Murphy or Richard A. Baldwin, Division of Field Science (HFC–141), 5600 Fishers Lane, rm. 12–41, Rockville, MD 20857, 301–443–3320, FAX 301–443–6388.

SUPPLEMENTARY INFORMATION: This dialogue will be accomplished by the submission of topics by participants. Topics should be submitted with a justification for their relevance and significance within the pharmaceutical industry. All topics will be considered for their inclusion into the meetings. After each meeting, a report will be prepared and made available to the public.

I. Background

On March 28, 1996, members of the pharmaceutical industry and FDA came together to informally discuss practical problems associated with laboratory aspects of the development and monitoring of pharmaceutical products. Prior to this, a series of meetings was held in the Mid-Atlantic region on December 15, 1994, February 24, May 1, and July 20, 1995. Following are the topics of meetings that were held in the Mid-Atlantic Region. Topics previously discussed locally can be revisited in the future if there is an interest.

A. Topics That Have Been Discussed Previously in the Mid-Atlantic Region

Topics that have been discussed previously are laboratory computer validation, laboratory automation and robotics, computer systems and subsystem validations, validation of software updates, vendor support of outdated software, integrity of data in electronic signatures, regulatory requirements for electronic signatures, bar coding technology, systems for sample tracking, installation qualification (IQ), operation qualification (OQ), and performance qualification (PQ) of laboratory instruments.

On March 28, 1996, the meeting was convened by FDA's facilitator Richard A. Baldwin, Director, Division of Field Science. Gerald E. Vince, Director, Office of Regional Operations, gave the opening remarks and indicated that communication is beneficial to FDA and industry. Several presentations were given: Jeanne White from the Office of the Commissioner spoke about previous grassroots exercises and how successful they have been and Marie Urban, ORA 21 Coordinator, spoke on various initiatives by ORA in response to the Clinton Administration's National Performance Review and the Government Performance and Results Act of 1993. To conclude the presentations, James Farley, Director of the Philadelphia District Laboratory, gave background information as to how the discussion group came into existence.

An open dialogue was initiated as to how the discussion group should proceed and what the shared expectations should be for the group. The guiding principles and the items that emerged from the meeting are listed below.

B. Meeting Objectives (Guiding Principles)

One of the primary purposes of the discussion group is information sharing, which is vital for future success. At the March 28, 1996 meeting, it was suggested that FDA work with the trade associations to disseminate information, and utilize the associations as a vehicle for eliciting a priority list of topics from industry. Discussions will be open to all of the pharmaceutical industry and others so that everyone who is interested can participate. Another vehicle which was suggested was the use of the Internet and the FDA homepage for announcing the meetings and sharing information. Other suggestions for sharing information included focus groups, roundtable discussions, forums, and working groups.

The overall purpose of these meetings is to facilitate discussion and get a better understanding of expectations. The intent is a 360 degree understanding in context of flexibility—understanding the breath and depth of an issue from the various perspectives. There was an overall consensus that if there were a better understanding of each others situations, the agency and industry could work together to provide safer products to consumers.

II. Laboratory Issues: New Topics

Some laboratory issues and new topics that may be addressed at future meetings include the following: Identifying the acceptable ''best practices,'' research/quality assurance (QA), acceptable uses of technology, changes in technology, and pharmaceutical science-data integrity. FDA is interested in hearing whether there is interest in discussing these topics, as well as suggestions for other topics, by November 8, 1996.

Dated: October 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–27678 Filed 10–28–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the Special Programs Emphasis Panel of the Office of the Director, National Institutes of Health.

The Special Programs Emphasis Panel of the Office of the Director, National Institutes of Health will provide advice and guidance to the Director, NIH, and other Federal officials in special areas of scientific programmatic need.

Unless renewed by appropriate action prior to its expiration, the Special Programs Emphasis Panel of the Office of the Director, National Institutes of Health will terminate two years from the date of establishment.

Dated: October 21, 1996.

Harold Varmus,

Director, National Institutes of Health.

[FR Doc. 96–27632 Filed 10–28–96; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Notice of Meeting

Notice is hereby given of the meeting of the National Cancer Institute Board of Scientific Advisors on November 21–22, 1996 in Conference Room 10, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland.

This meeting will be open on November 21 from 8:30 am to approximately 5 pm and on November 22 from 8:30 am to adjournment at 1 pm. Agenda items will include: NCI Director's Report; Board operating procedures and representation at scientific meetings; presentation and discussion on how NCI distributes RPG funds and the RFA and contract support mechanisms; Board working group updates, presentation on the Cancer Genone Anatomy Project, and concept