Respondents	No. of respondents	No. of responses/ respondent	Average burden/ response (in hrs)
D. Followback for evaluations without onsite evaluations:			
Year 1	75	1	10/60
Year 2	75	1	15/60

Dated: August 10, 2004.

Alvin Hall,

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

[FR Doc. 04–18677 Filed 8–13–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Public Consultation

AGENCY: Administration for Native Americans (ANA).

ACTION: Notice of Public Consultation.

SUMMARY: The Administration for Children and Families (ACF) will be holding a half-day Tribal Consultation Session on September 20, 2004 at the Rayburn House Office Building in Washington, DC.

DATES: September 20, 2004.

FOR FURTHER INFORMATION CONTACT: Kim Vigue, Administration for Native Americans, toll free at 1–877–922–9262 or *www.masterkeyconsulting.com/acfconference.*

SUBMISSION INFORMATION: Tribal leaders and representatives interested in submitting written testimony or topics to be discussed on the Consultation Session agenda should contact Kim Vigue toll free at 1–877–922–9262.

If you are proposing a topic to be addressed in the Consultation Session, please be sure to include a brief description of the topic area along with the name and contact information of a suggested presenter.

The public record will remain open for 60 days following the September 20, 2004 consultation. Written comment and testimony can be submitted until November 19, 2004.

SUPPLEMENTARY INFORMATION:

The Administration for Children and Families would like to invite Tribal leaders to participate in a formal consultation Session with ACF senior officials and program directors. The Consultation Session will take place Monday, September 20, 2004 from 8:30 a.m. to 12:30 p.m. in Rayburn House Office Building Room B–339.

The intent of this Consultation Session is to allow ACF officials to hear first hand from Tribal leaders and representatives of Tribal organizations and Native Americans non-profit organizations about the implementation of ACF programs in Native Americans communities. Of particular interest are the challenges that Tribes and Tribal organizations face in accessing ACF program funding and using program funding to support social and economic development activities in Native American communities. ACF offices such as the Administration for Native Americans, Office of Child Support Enforcement, Office of Community Services, Office of Family Assistance, Child Care Bureau, Children's Bureau, Head Start Bureau, and the Family and Youth Services Bureau will be represented.

Because of the limited time, ACF has collaborated with Master Key Consulting to plan and facilitate the session. Master Key Consulting will be responsible for coordinating the stakeholders who wish to participate in the Consultation Session and will work with a planning committee to develop a structured agenda, identifying key issues to be raised and spokespersons to present testimony on the issues.

Dated: August 6, 2004.

Quanah Crossland Stamps,

Commissioner, Administration for Native Americans.

[FR Doc. 04–18588 Filed 8–13–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0355]

Scientific Considerations Related to Developing Follow-On Protein Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop on scientific and technical considerations related to the development of follow-on protein pharmaceutical products. The agency is planning to develop draft guidance on this topic during the coming year. The purpose of this workshop is to obtain input from interested persons on the topics outlined in this document related to developing and approving follow-on protein pharmaceutical products. The agency will consider presentations made at the workshop and comments submitted to the docket before and after the workshop when developing the draft guidance.

DATES: The public workshop will be held on Tuesday, September 14, 2004, from 8:30 a.m. to 5 p.m. and Wednesday, September 15, 2004 from 8 a.m. to 12 noon. Submit requests to make a presentation by September 7, 2004.

ADDRESSES: The public workshop will be held at the University of Maryland—Shady Grove Conference Center, 9630 Gudelsky Dr., Rockville, MD 20850.

Submit written comments on scientific topics related to follow-on protein products to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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.

FOR FURTHER INFORMATION CONTACT:

To register to present: Marilyn Welschenbach, Center for Drug Evaluation and Research (HFD–121), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–443–5089, FAX: 301–443–5245, e-mail: *Marilyn.Welschenbach@fda.gov.*

With regard to the scientific topics outlined in this notice: Keith Webber, Center for Drug Evaluation and Research, Food and Drug Administration (HFD–121), 5600 Fishers Lane, Rockville, MD 20852, 301–443–5089, FAX: 301–443–5234, e-mail: *Keith.Webber@fda.gov*, or Chris Joneckis, Center for Biologics Evaluation and Research (HFM–1),

Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20892, 301–827–2000, e-mail: *Christopher.Joneckis@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

During the past several years, FDA has received numerous inquiries concerning how a sponsor may scientifically demonstrate that its protein pharmaceutical product is similar enough to a product that FDA has licensed under the Public Health Service (PHS) Act or approved under the Federal Food, Drug, and Cosmetic Act to obtain licensure or approval without conducting certain studies that would otherwise be necessary. This public workshop is not intended to address legal or regulatory issues. Because of the scientific complexity of protein pharmaceutical products, FDA intends to conduct an extensive public dialogue on the scientific issues relating to the development and approval of such products. For the purposes of this workshop, we use the term ''follow-on protein product'' to refer to a protein that is intended to be a similar version or copy of an already approved or licensed protein pharmaceutical product. Such proteins might be produced through biotechnology or derived from natural sources. (This public workshop is not intended to address ''second-generation protein products'' which we have tentatively defined as products that are similar to an already approved or licensed product but which have been deliberately modified to change one or more of the product's characteristics (e.g., to provide more favorable pharmacokinetic parameters or to decrease immunogenicity)). This public workshop is concerned only with scientific issues relating to follow-on protein products.

On March 16, 2004, in its Critical Path report, available at *http://www.fda.gov/oc/initiatives/criticalpath*, FDA announced an initiative to identify the problems and some potential solutions to ensure that breakthroughs in medical science can be translated to safe, effective, and available medical products. In the report, FDA underscored the importance of FDA collaboration with academic researchers, product developers, patient groups, and other stakeholders to make the critical path more predictable and less costly. Consistent with the Critical Path Initiative, FDA is seeking input from its broad stakeholder community as it begins the process of exploring the scientific framework for developing and approving follow-on protein products.

II. Information on the Public Workshop

A. Why Are We Holding This Public Workshop?

It is critical that the agency solicit the scientific and technological perspectives of manufacturers, academia, and other interested persons to determine the state of the science as it relates to protein characterization, production, and assessment of similarity. Such information will be critical to any guidance on follow-on protein products.

B. Where Will This Public Workshop Be Held?

University of Maryland—Shady Grove Conference Center, 9630 Gudelsky Dr., Bldg. II, rm. 1422, Rockville, MD 20850.

C. When Will This Public Workshop Be Held?

The public workshop will be held on September 14, 2004, from 8:30 a.m. to 5 p.m. and September 15, 2004, from 8 a.m. to 12 noon.

D. How Will the Public Workshop Be Organized?

The agency is seeking input on a series of scientific topics (see section III of this document) and is asking interested persons to make presentations on these and other pertinent scientific topics. A panel of agency experts will listen to the presentations organized by the categories listed in section III of this document, after which they may ask followup questions of the presenters.

E. How Can I Participate?

1. In Person

Persons who wish to make a presentation during the public workshop must file an electronic, written, or facsimile notice of participation with Marilyn Welschenbach by September 7, 2004 (see **FOR FURTHER INFORMATION CONTACT**). The notice of participation shall contain the speaker's following information:

- Name
- Title
- Business affiliation, if any
- Address
- Telephone number
- Fax number
- A brief summary of the presentation
- Designate topic categories A through F (see section III of this document) for the presentation
- Approximate amount of time requested for the presentation (presentations should be limited to 10 minutes in duration).

We recommend that individuals and organizations with common interests consolidate or coordinate their presentations and request time for a joint presentation. After registration has closed, FDA will inform participants of the amount of time available for their presentations based on the final agenda and on which day they will be scheduled to present. Persons requiring a sign language interpreter or other special accommodations should notify Marilyn Welschenbach by September 1, 2004.

2. In Writing

FDA has established a public docket for comments. Comments can be submitted until November 12, 2004. It is important that comments submitted to the docket be identified with the docket number found in brackets in the heading of this document. Submit written comments to the Division of Dockets Management (see **ADDRESSES**).

F. Is There a Registration Fee for This Public Workshop?

There is no registration fee for this public workshop.

G. What if I Have Scientific or Logistical Questions?

If you have any logistical questions about the public workshop, please contact Marilyn Welschenbach; scientific questions may be addressed to Keith Webber or Chris Joneckis. Contact information is listed under the **FOR FURTHER INFORMATION CONTACT** section of this document.

H. Can I Get a Transcript of This Public Workshop?

A transcript of the public workshop will be available from the Division of Dockets Management, approximately 15 business days after the workshop at a cost of 10 cents per page. The transcript of the workshop will also be available for public examination at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Background Information

FDA seeks comment on the following topics and other scientific issues related to follow-on protein products:

A. Manufacturing Issues

1. What aspects of the manufacturing process determine the characteristics of a protein product whether produced through biotechnology or derived from natural sources?

2. What parts of the manufacturing process should the agency focus on when assessing similarity between products?

B. Characterization

1. What is the capability of current analytical technology to adequately characterize protein products?

2. Are there new technologies that hold promise for helping to characterize proteins?

3. What factors, including quality attributes, impurity profiles, and changes in the manufacturing process, should be considered when assessing similarity of different protein products?

4. Is it possible to accurately predict safety and efficacy from analytical studies?

C. Immunogenicity

1. How, and to what extent, should immunogenicity be evaluated for a follow-on protein product?

2. Under what circumstances should comparative immunogenicity studies be conducted?

D. Preclinical and Clinical

1. When and how would it be appropriate to streamline or eliminate certain animal or human studies during development of a follow-on protein product?

E. Potency and Surrogates for Efficacy and Safety

1. What factors should be considered regarding bioactivity and potency assays used for comparing two products?

2. What is the role of in vitro and in vivo assays for use as surrogates in establishing safety and efficacy?

F. Terminology

1. Please comment on the appropriateness of this notice's working definition of ''follow-on protein'' as a protein that is intended to be a similar version or copy of an already approved or licensed protein pharmaceutical product.

2. Please comment on this notice's working definition of a ''second-generation protein product'' as a product similar to an already approved or licensed product but which has been deliberately modified to change one or more of the product's characteristics (e.g., to provide more favorable pharmacokinetic parameters or to decrease immunogenicity).

Dated: August 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–18627 Filed 8–11–04; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0361]

Guidance for Industry: Prior Notice of Imported Food Contingency Plan for System Outages; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a contingency plan that provides guidance on submitting prior notice of imported food during system outages affecting the applicable FDA and Customs and Border Protection (CBP) program systems. Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and its implementing regulations require prior notice to FDA of all food imported or offered for import into the United States.

DATES: This guidance is final upon the date of publication. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent.

Submit written comments on the 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Domenic Veneziano, Office of Regulatory Affairs (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 703–621–7809.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58974), FDA issued an interim final rule (IFR) to implement section 307 of the Bioterrorism Act. The prior notice IFR requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. The prior notice IFR provides that if a customs broker's or self-filer's system is not working or if the Automated Broker Interface of the Automated Commercial System is not working, prior notice must be submitted through the Prior Notice System Interface (PNSI); and that if PNSI or the Operational and Administrative System for Import Support is not operating, prior notice information must be submitted by e-mail or by fax to FDA.

We stated in the prior notice IFR that FDA does not plan to exempt any specific categories of food articles from prior notice if system(s) are not working, and that FDA and CBP are working together to develop contingency plans for when the applicable FDA and CBP program systems are not working (68 FR 58974 at 58997). FDA with concurrence from CBP is announcing the availability of a contingency plan that provides guidance on submitting prior notice of imported food during system outages affecting the applicable FDA and CBP program systems. The contingency plan identifies seven potential system downtime scenarios that could impact transmission, confirmation, and processing of prior notice submissions and explains recommended submission options for each of the identified scenarios. In any of the scenarios described in the contingency plan, where the alternate submission options include both e-mail and fax (telephonic facsimile) transmissions, e-mail transmission is strongly encouraged as the more efficient means.

FDA is issuing this document as a level 1 guidance consistent with FDA's good guidance practices regulation (§10.115 (21 CFR 10.115)). The contingency plan is being implemented immediately without prior public comment, under §10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. Under section 307 of the Bioterrorism Act, the prior notice requirements were effective December 12, 2003, and FDA and CBP's systems for processing prior notice submissions are up and running, making it urgent that the agencies explain how submitters can fulfill the prior notice requirements in the event of system outages.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance document. Submit two copies of written comments, except that individuals may submit one