DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314, 600, and 601

[Docket No. 95N–0329]

RIN 0910–AA57

Changes to An Approved Application; Proposed Rule and Draft Guidance Documents; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the proposed amendments to the biologics regulations for reporting changes to an approved application and corresponding drug regulations for submitting supplements for and reporting changes to an application for well-characterized biotechnology products. The purpose of the meeting is to solicit information and views on the agency's proposed rule addressing reporting of changes to an approved application as well as discuss the material and categories set forth in the closely related draft guidance documents.

DATES: The public meeting will be held on Friday, April 19, 1996, from 8 a.m. to 5 p.m. Submit written notices of participation, including a brief summary of the presentation and approximate time requested, by April 15, 1996. Written comments will be accepted until May 6, 1996.

ADDRESSES: The public meeting will be held at the National Institutes of Health, Bldg. 10, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Attendance may be limited to 500, which is the capacity of the auditorium. Submit written notices of participation and comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. FDA requests that persons who intend to participate notify the agency in advance. To expedite processing, written notices of participation may also be FAXED to 301–827–3843. 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. Transcripts of the meeting will be available for review at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: For information regarding the meeting or to advise FDA of an intent to participate: Margaret A. Tart, Center for Biologics Evaluation and Research (HFM–42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–2000, FAX 301–827–3843.

For information regarding this document: Tracey H. Forfa, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 29, 1996 (61 FR 2739), FDA announced its intent to hold a public meeting during the pendency of the comment period that ends on April 29, 1996, for the proposal to amend the biologics regulations for reporting changes to an approved application and corresponding drug regulations for submitting supplements for and reporting changes to an application for well-characterized biotechnology products (21 CFR 314.70 and 601.12). During this public meeting FDA is seeking comments on the proposed mechanisms for reporting changes to an approved application. Specifically, FDA is seeking comments on the three-category scheme for reporting changes in the product, production process, equipment, facilities, or responsible personnel. The three categories would include: (1) Supplement submission and approval prior to distribution of a product made using a proposed change that has a substantial potential to have an adverse effect on a product's safety, purity, potency, or effectiveness; (2) notification not less than 30 days prior to distributing a product made using a proposed change that has a moderate potential to have an adverse effect on a product's safety, purity, potency, or effectiveness; and (3) an annual report describing changes that have minimal potential to have an adverse effect on a product's safety, purity, potency, or effectiveness.

Further, FDA is asking for comment on the proposed three-category reporting system for biological product labeling changes. A change to a product package label, container label, or package label would require one of the following: (1) Submission of a supplement with FDA approval required prior to product distribution; (2) submission of a supplement with product distribution allowed prior to FDA approval; or (3) submission of the final printed label in an annual report. Promotional labeling and advertising would be required to be submitted under procedures found at 21 CFR 314.81(b)(3)(i).

In addition, FDA is seeking public comment on the draft guidance documents, ''Changes to An Approved Application; Draft Guidance'' and ''Draft Guidance; Changes to An Approved Application for Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products,'' that were made available concurrently with the proposed rule in the Federal Register of January 29, 1996 (61 FR 2748 and 2749). FDA is seeking comments on the categorization of changes in the draft guidance documents and also on the utility of the guidance documents to applicants. FDA is not, however, intending to use this forum for additional discussion of the agency's definition of a well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology product that was originally announced in the Federal Register of December 8, 1995 (60 FR 63048).

The procedures governing the meeting can be found in 21 CFR part 15. Prior to the meeting, FDA will determine the amount of time assigned to each person and the approximate scheduled time for each presentation. A schedule showing the persons making presentations will be filed with the Dockets Management Branch (address above), and mailed or FAXED to each presenter before the meeting. Interested persons attending the meeting who did not request an opportunity to make a presentation will be given the opportunity to make an oral presentation at the conclusion of the meeting, as time permits. However, no participant may interrupt the presentation of another participant.

Comments received at the public meeting and written comments submitted to the Dockets Management Branch (address above) by May 6, 1996, will be considered in the review of the proposed rule and guidance documents to determine whether revisions are warranted. After careful review of the public comments, FDA intends to revise the draft guidance documents, if necessary, and publish a final rule.

Dated: March 25, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–7613 Filed 3–25–96; 4:06 pm]

BILLING CODE 4160–01–F

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Chapter XIV

Older Workers Benefit Protection Act of 1990 (OWBPA)

AGENCY: Equal Employment Opportunity Commission (EEOC).

ACTION: Fourth meeting of Negotiated Rulemaking Advisory Committee.

SUMMARY: EEOC announces the dates of the fourth meeting of the ''Negotiated Rulemaking Advisory Committee for Regulatory Guidance on Unsupervised Waivers of Rights and Claims under the Age Discrimination in Employment Act'' (the Committee). A Notice of Intent to form the Committee was published in the Federal Register on August 31, 1995, 60 FR 45388, and a Notice of Establishment of the Committee was published in the Federal Register on October 20, 1995, 60 F.R. 54207.

DATES: The fourth meeting will be held on April 16–17, 1996, beginning at 10:00 a.m. on April 16. It is anticipated that the meeting will last for two days. The session of April 17, 1996 will commence at 9:00 a.m.

ADDRESSES: The meeting will be held at the EEOC Headquarters, 1801 L Street, N.W., Washington, D.C. 20507.

FOR FURTHER INFORMATION CONTACT: Joseph N. Cleary, Paul E. Boymel, or John K. Light, ADEA Division, Office of Legal Counsel, EEOC, 1801 L Street, N.W., Washington, D.C. 20507, (202) 663–4692.

SUPPLEMENTARY INFORMATION: All Committee meetings, including the meeting of April 16–17, will be open to the public. Any member of the public may submit written comments for the Committee's consideration, and may be permitted to speak at the meeting if time permits. In addition, all Committee documents and minutes will be available for public inspection in EEOC's Library (6th floor of the EEOC Headquarters).

Persons who need assistance to review the comments will be provided with appropriate aids such as readers or print magnifiers. To schedule an appointment call (202) 663–4630 (voice), (202) 663–4630 (TDD). Copies of this notice are available in the following alternate formats: large print, braille, electronic file on computer disk, and audio tape. Copies may be obtained from the Office of Equal Employment Opportunity by calling (202) 663–4395 (voice), (202) 663–4399 (TDD).

Purpose of Meeting/Summary of Agenda

At the meeting, the Committee will continue to discuss the unsupervised waiver legal issues that will be considered by the Committee in drafting a recommended notice of proposed rulemaking for EEOC approval.

Dated: March 23, 1996.

Frances M. Hart,

Executive Officer.

[FR Doc. 96–7471 Filed 3–27–96; 8:45 am]

BILLING CODE 6570–06–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 220 and 227

[FRL–5449–4]

RIN 2040–AC81

Extension of Time for Receipt of Comments on Proposed Rule on Testing Requirements for Ocean Dumping

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of time for receipt of comments on proposed rule on testing requirements for ocean dumping.

SUMMARY: On February 29, 1996, EPA published a proposed rule at 61 FR 7765, clarifying certain provisions of the Agency's ocean dumping regulations relating to testing provisions of the regulations. The proposal stated that written comments on the proposed rule would be accepted until April 1, 1996. EPA has received several requests for an extension of time to comment on the proposed rule, on the grounds that several issues that the rule addresses require additional time for analysis. The Agency has determined that an extension of time is in the public interest, and that an additional 30 days to comment on the proposed rule is reasonable. Consequently, the period for receipt of comments on the proposed rule is extended until May 1, 1996.

DATES: The comment period is extended until May 1, 1996.

It should be noted that this extension of time for comment neither represents any modification of the proposed rule, nor indicates a change in the Agency's interpretation of the existing requirements under the ocean dumping regulations. The extension of time for receipt of comments simply provides those interested parties an additional 30 days to provide comments to the Agency on the proposed rule. All other requirements stipulated in the initial proposal for receipt of comments still apply.

FOR FURTHER INFORMATION CONTACT: John Lishman, Chief, Marine Pollution Control Branch, Oceans and Coastal Protection Division (4504F), Environmental Protection Agency, 401 M Street, SW, Washington, DC, 20460, telephone 202/260–8448.

Dated: March 22, 1996.

Robert Perciasepe,

Assistant Administrator.

[FR Doc. 96–7606 Filed 3–27–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 300

[FRL–5447–7]

National Oil and Hazardous Substances Pollution Contingency Plan National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of intent to delete Howe Valley Landfill Superfund Site, Hardin County, Kentucky, from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region 4 announces its intent to delete the Howe Valley Landfill Site (the Site) from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL constitutes Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), as amended. EPA and the Commonwealth of Kentucky have determined that the responsible parties have implemented all appropriate response actions required at the Site and therefore, further remedial measures pursuant to CERCLA are not appropriate.

DATES: Comments may be submitted by midnight April 30, 1996.

ADDRESSES: Comments may be mailed to: Nestor Young, Remedial Project Manager, North Superfund Remedial Branch, U.S. Environmental Protection Agency, Region 4, 345 Courtland Street, N.E., Atlanta, GA 30365.

Comprehensive information on this Site is available through the public docket which is available for viewing at the Howe Valley Landfill Site information repositories at the following locations:

Hardin County Public Library, 201 West Dixie Avenue, Elizabethtown, KY, 42701.