the Substance Abuse and Mental Health Services Administration (SAMHSA) National Advisory Council in January 1996.

The meeting of the SAMHSA National Advisory Council will include discussions concerning SAMHSA's Reauthorization; update on SAMHSA's demonstration program; SAMHSA's Managed Care Initiative, including the role of SAMHSA in developing mental health and substance abuse standards for managed care facilities; report on the Performance Partnership Development Process and Regional Meetings; and a report on the Co-Occurring Meeting. In addition various constituency organizations will be describing their collaborative efforts around the development of performance measures and outcomes monitoring, and exemplary community based programs will be describing their efforts to prevent and treat mental and addictive disorders. Finally, there will be status reports by the Council's work groups on Health Care Reform and Children's Services. Attendance by the public will be limited to space available.

The meeting will also include the review, discussion and evaluation of contract proposals. Therefore a portion of the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c) (3), (4) and (6) and 5 U.S.C. app. 2 10(d).

A summary of the meeting and a roster of Council members may be obtained from: Ms. Susan E. Day, Program Assistant, SAMHSA National Advisory Council, 5600 Fishers Lane, Room 12C–15, Rockville, Maryland 20857. Telephone: (301) 443–4640.

Substantive program information may be obtained from the contact whose name and telephone number is listed below.

Committee Name: Substance Abuse and Mental Health Services Administration, National Advisory Council.

Meeting Date: January 22, 1996.

Place: Omni-Shoreham Hotel, 2500 Calvert Street, N.W., Washington, DC 20008.

Open: January 22, 1996, 9:00 a.m. to 4:30 p.m.

Closed: January 22, 1996, 5:00 p.m. to 6:00 p.m.

Contact: Toian Vaughn, Room 12C–15, Parklawn Building, telephone (301) 443–4640 and FAX (301) 443–1450.

Dated: December 4, 1995.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 95–29934 Filed 12–7–95; 8:45 am]

BILLING CODE 4162–20–P

Food and Drug Administration

[Docket No. 95N–0371]

Interim Definition and Elimination of Lot-by-Lot Release For Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an interim definition for well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. FDA is also announcing that FDA is eliminating lot-by-lot release for licensed well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. After approval, manufacturers of such products are no longer requested to submit samples and protocols for individual lots of products to the Center for Biologics Evaluation and Research (CBER) for routine lot-by-lot release. Manufacturers may begin distributing products affected by this policy after notification by CBER and without awaiting approval of a supplement to their product license applications. This notice is intended to reduce unnecessary burdens for industry without diminishing public health protection.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Regarding lot release: Jerome A. Donlon, Center for Biologics Evaluation and Research (HFM–200), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–2200.

Regarding the definition of a well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology product: Jean M. Olson, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: This notice is being issued in accordance with the principles set forth in Executive Order 12866. Executive Order 12866 directs Federal agencies to implement measures that will reform and streamline the regulatory process to avoid unnecessary regulatory burdens. In the November 1995 ''Reinventing the Regulation of Drugs Made from Biotechnology'' report, the President and Vice President announced a series of regulatory reform initiatives, including FDA's intention to issue a notice eliminating lot-by-lot release for licensed well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. FDA made a commitment to issue the notice within 30 days of the report.

Elimination of Lot-by-Lot Release

Biologics have traditionally been complex mixtures of substances produced primarily from living organisms, and have been difficult to characterize by precise tests. They include vaccines, products made from human or animal blood, and other products made from a variety of materials. Because of the inherent variability of these products, each individual lot of most biological products has been subject to evaluation and testing by CBER prior to release.

Under § 610.2 (21 CFR 610.2), the Director of CBER may require, at any time, that samples of a licensed product, protocols, and test results be submitted to CBER for official release. FDA has invoked lot-by-lot release to help ensure that products continue to meet established standards before they are distributed.

Historically, lot-by-lot release has served an important role in the regulation of biotechnology products and has prevented the distribution of unacceptable lots. However, greater control has been achieved by manufacturers over the production of biotechnology products through in-process controls, process validation, and advances in analytical techniques. For well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products, as defined below, FDA has found that once a company has demonstrated its ability to consistently produce acceptable lots, and has procedures in place that will prevent the release of lots that do not meet release specifications, it is not necessary for FDA to verify that each

manufactured lot is acceptable for release.

Accordingly, as provided under § 610.2, the Director of CBER is no longer requiring that manufacturers of well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products submit samples and protocols to CBER. FDA will continue to monitor companies' compliance with the requirement in § 610.1 (21 CFR 610.1) that they assay each lot and release only those lots that meet release specifications.

FDA intends to revise the guidance entitled, ''Guidance on Alternatives to Lot Release for Licensed Biological Products,'' (58 FR 38771, July 20, 1993) to reflect the new procedures. Manufacturers who do not receive a letter, but think that one of their licensed products meets the interim definition, may contact Jerome A. Donlon (address above).

Eliminating FDA lot-by-lot release should not compromise the safety, purity, or potency of licensed well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. Because of process validation and current in-process controls and testing for these products, identity, purity, and potency can be controlled and measured. In addition, the in-process and end-product release specifications can be validated for these products. Therefore, submission of lot release samples and protocols are no longer viewed by FDA as essential to the ongoing assurance of safety for these products.

Eliminating lot-by-lot release for these products furthers FDA's harmonization of its regulation of well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products between CBER and the Center for Drug Evaluation and Research.

Manufacturers are still required under § 610.1 to test each lot and release only those that meet release specifications. During inspections, FDA will monitor compliance with those requirements. Manufacturers continue to be required to maintain adequate records and retention samples under 21 CFR 211.170 and 211.180.

Interim Definition

FDA has prepared the following interim definition for a well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology product:

A chemical entity(ies) whose identity, purity, impurities, potency, and quantity can be determined and controlled.

Identity:

a. *Recombinant DNA Biotechnology Products*

The primary structure is known (i.e., amino acid sequence), and

The secondary structure is known (e.g., disulfide linkage), and

Post-translational modifications are known (e.g., glycosylation), or

b. *Monoclonal Antibodies*

The identity can be determined by rigorous physicochemical and immunochemical characterization without fully knowing its chemical structure.

Purity and impurities:

The purity is quantifiable.

The impurities are quantifiable, and identified if feasible.

Potency and quantity:

The biological activity is measurable.

The quantity is measurable.

Well-characterized therapeutic recombinant DNA-derived or monoclonal antibody biotechnology products require proper raw material controls, process validation and controls, and sensitive and validated test methods and specifications. FDA intends to use the definition to determine which products may be exempted from lot-by-lot release and to help determine which products may be eligible for other regulatory initiatives directed at well-characterized biotechnology products.

FDA invites comments on its proposed definition for well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. In particular, FDA invites comments on whether the proposed definition for well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products should be expanded to include other categories of products that would be considered to be well-characterized and should be categorically exempted from lot-by-lot release.

In the Federal Register of October 25, 1995 (60 FR 54695), FDA announced that it is sponsoring a public scientific workshop on December 11 through 13, 1995. At the workshop participants will be asked to refine the definition of a well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology product as set forth above. After considering the information presented at the workshop, FDA may modify the interim definition given above. Manufacturers of well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products affected by this change in policy will be notified by letter.

CBER does not intend for this notice to be comprehensive. If a manufacturer has questions concerning application of this policy to one of its licensed products or the interim definition, it can discuss the matter with CBER. Although the interim definition for well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products in this notice is not binding on either FDA or manufacturers of biological products and does not create or confer any rights for or on any person, it does represent the agency's current thinking on that definition.

Dated: December 4, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–29960 Filed 12–5–95; 2:43 pm]

BILLING CODE 4160–01–F

[Docket No. 93N–371W]

Prescription Drug Product Labeling; Public Patient Education Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public patient education workshop to discuss methods and criteria for developing and evaluating prescription drug information for patients. The purpose of this workshop is to obtain views and opinions concerning the criteria for useful patient information, and is part of FDA's ongoing initiative to improve the distribution of adequate and useful prescription drug information to patients. FDA encourages health professionals, consumer groups, industry, academicians, other experts in the field, and interested parties to participate in the workshop. FDA also invites the designers of primary information systems, which produce either written information or computer programs that generate prescription drug patient information, to display their systems for educational purposes.

DATES: The public patient education workshop will be held on January 9 and 10, 1996, from 8:30 a.m. to 5 p.m. Submit registration notices for participants by December 26, 1995. Submit registration notices for designers of information systems by December 19, 1995. Submit written comments by January 31, 1996.

ADDRESSES: The public patient education workshop will be held at the National Institutes of Health, Natcher Auditorium, 9000 Rockville Pike, Rockville, MD. Pre-registration for workshop participants is encouraged, although not required, in order to facilitate logistical planning of the