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