those proposed in this document. Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The regulation proposed in this document will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act (21 U.S.C 342), and the failure of any person to come forward with proof of such an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on the sanction at any later time. This notice also constitutes a proposal to establish a regulation under Part 181 (21 CFR Part 181), incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to this proposal.

Interested persons may, on or before August 21, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order.

Dated: June 14, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-19315 Filed 6-21-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 345]

[Docket No. 78N-0024]

Vitamin and Mineral Drug Products for Over-the-Counter Human Use; Proposed Rulemaking; Extension of Time for Comments and Reply Comments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule; Extension of comment periods.

SUMMARY: The Food and Drug Administration (FDA) extends to July 16, 1979, the comment period and to September 14, 1979, the reply comment period on the proposal to establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) vitamin and mineral drug products. The action is being taken to allow more time for the collection and assessment of data to provide more meaningful comments on the issue.

DATE: Written comments by July 16, 1979, and reply comments by September 14, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 16, 1979 (44 FR 16126), FDA proposed to establish conditions for the safety, effectiveness, and labeling of vitamin and mineral durg products for over-the-counter (OTC) human use. The proposed rule, based on the recommendations of the Advisory Review Panel on Vitamin, Mineral, and Hematinic Drug Products, is part of the ongoing review of OTC drug products conducted by the agency. Interested persons were given until June 14, 1979 to comment on the proposal and until July 16, 1979 for reply comments.

In response to the proposal, the firm of Bass, Ullman and Lustigman, on behalf of the National Association of Pharmaceutical Manufacturers and the National Nutritional Foods Association, requested a 30-day extension of the comment period and a 60-day extension of the reply comment period. Another request, on behalf of the Council for Responsible Nutrition asked for a 45-day extension of the comment period. The requests for extension of the comment period were to develop a response that would focus attention on the controversial issues in the proposal in an attempt to remove these areas of controversy to the maximum extent feasible and to permit time to obtain member consensus on the issues, respectively. The request for an extension of the reply comment period was based on delays experienced by the firm in obtaining copies of relevant comments.

The agency has carefuly considered the requests and notes that an unusually large number of comments have been received in response to the proposal. The number received has been in excess of 1,800 and represents the largest number of comments received in response to any proposal on OTC drug products. The agency, therefore, considers an extension of the comment and reply comment periods appropriate. The agency believes, however, that a 30-day extension of the comment period should provide sufficient time for all interested persons to develop meaningful comments on this proposal.

Accordingly, the comment period is extended to July 16, 1979, and the reply comment period is extended to September 14, 1979. Comments may be seen in the office of the Hearing Clerk, Food and Drug Administration, at the address noted above, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 14, 1979.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-19104 Filed 6-15-79; 12:05 pm]

BILLING CODE 4110-03-M

[21 CFR Part 510]

[Docket No. 78N-0206]

Records and Reports on New Animal Drugs and Antibiotics That Were Approved Before June 20, 1963

Correction

In FR Doc. 79-9842 appearing on page 19438 in the issue for Tuesday, April 3, 1979, an incorrect date was given in the heading. The correct date appears in the heading above.

Also, in the middle column, under the heading, "SUMMARY", the following correction should be made: In the 9th line, substitute the word "to" for the word, "of".

Finally, in the last column, at the end of the document, the docket number given is incorrect. The correct docket number appears in the heading above.

BILLING CODE 1505-01-M