c. This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration, and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

d. The Department of Defense shall forward to the General Services Administration copies of its testimony and briefs within 60 days of formal submission.

Dated: April 28, 1981.

Ray Kline,

Acting Administrator of General Services.

[FR Doc. 81-13435 Filed 5-4-81; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 76N-0052]

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter (OTC) Human Use; Decision on Dosage of Pseudoephedrine Preparations

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is extending until further notice the date by which manufacturers of OTC oral nasal decongestant drug products containing pseudoephedrine are required to comply with FDA's revised hourly dosage interval. The effective date changing the hourly dosage interval from 60 milligrams (mg) every 4 hours to 60 mg every 6 hours is being stayed in response to a petition from three manufacturers who submitted new pharamcokinetic and safety data to show that the hourly dosage interval should be every 4 to 6 hours. However, required revised labeling reflecting the agency's decision to reduce the maximum daily dosage of pseudoephedrine preparations in the proposed monograph for OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products will not be stayed and will become effective May 1, 1981.

DATE: The effective date for required relabeling for the maximum daily dosage is May 1, 1981. The effective date for required relabeling for the hourly dosage interval is stayed until further notice, pending review of new data.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 30, 1980 (45 FR 64709), FDA announced the decision that the available data did not support the 360-mg maximum daily dosage for drug products containing pseudoephedrine for OTC use as an oral nasal decongestant that had been recommended by the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Products. The notice explained that data submitted to the agency after the publication of the Panel's proposed monograph suggest that significant side effects could result from the 360-mg daily dosage and that a 240-mg maximum daily dosage is more appropriate. The agency concluded that, under the procedures established in 21 CFR 330.13(b)(2), pseudoephedrine products labeled with the higher dosage limitations would be required to be relabeled with specified lower dosage limitations by January 30, 1981.

In the **Federal Register** of December 19, 1980 (45 FR 83671), the agency granted two petitions and extended until May 1, 1981, the effective date for compliance with the revised dosage limitations that had been set forth in the September 30, 1980 notice.

On April 2, 1981, FDA received a petition from Schering Corp., The Dow Chemical Co., and Burroughs-Wellcome Co. requesting reconsideration of that part of the decision which extends the 60-mg dosage interval to every 6 hours. The petitioners sought adoption instead of a dosage interval of every 4 to 6 hours. The petitioners requested an extension of the May 1, 1981, effective date until such time as the pharmacokinetic and safety data which they submitted were evaluated, a decision with respect thereto issued, and a reasonable time thereafter was provided to enable them to revise the labeling for pseudoephedrine products to reflect the agency's final decision. A copy of the petition is on file in the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

The petitioners based their request on their belief that new pharmacokinetic and safety data on pseudoephedrine, both alone and in combination with other drugs, have shown that the major determinant of the half-life of pseudoephedrine is the pH of the urine in which pseudoephedrine is excreted. The petitioners believe that the data demonstrate that a flexible dosing schedule of every 4 to 6 hours is permissible and is more reflective of the achievable blood levels than the fixed dosage of every 6 hours established in the September 30, 1980 notice.

FDA has considered this request and has concluded that good and sufficient reason has been provided for staying until further notice the May 1, 1981 effective date for the revised dosage interval of 60 mg every 6 hours until the new data are reviewed. In the interim, pseudoephedrine products labeled either 60 mg every 4 hours or 60 mg every 6 hours will be permitted on the OTC drug market until the agency issues a decision on the appropriateness of an every 4- to 6-hour dosage interval.

The petitioners also state that they support the agency's decision to reduce the maximum adult dosage during a 24-hour period from 360 to 240 mg. The agency decided in the September 30, 1980 notice that a daily dosage in excess of 240 mg of pseudoephedrine may be associated with significant side effects without additional therapeutic benefit. Therefore, for safety reasons, required revised labeling reflecting the maximum daily OTC dosage of 240 mg for adults and corresponding maximum daily OTC dosages for children will not be stayed and will become effective May 1, 1981 as set forth in the September 30 and December 19, 1980 notices.

Dated: April 29, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-13445 Filed 4-30-81; 10:45 am]

BILLING CODE 4110-03-M

[Docket No. 81M-0110]

Medical Devices; Boehringer Mannheim Corp.; Premarket Approval of Synthograft™ Dental Implant

Corrections

In FR Doc. 81-11570 appearing on page 22462 in the issue of Friday, April 17, 1981, second column, "Synthograft" should have appeared in the heading as set forth above; third column, first line from the top, and in the fifth line of the first paragraph of the "SUPPLEMENTARY INFORMATION," "Synthograft" ® should have read "Synthograft ™".

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