of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. Section 172.841 is amended by redesignating paragraphs (b), (c), and (d) as paragraphs (c), (d), and (e), respectively, by adding new paragraph (b), and by revising newly redesignated paragraph (c) to read as follows:

§ 172.841 Polydextrose.

* * * * *

(b) The additive meets the specifications of the "Food Chemicals Codex," 3d ed. (1981), 2d supp. (1986), pp. 57–59, as amended by the 3d supp. (1992), p. 136, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Division of Product Policy (HFS-205), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) Polydextrose is used in accordance with current good manufacturing practices as a bulking agent, formulation aid, humectant, and texturizer in the following foods when standards of identity established under section 401 of the act do not preclude such use: Baked goods and baking mixes (restricted to fruit, custard, and pudding-filled pies; cakes; cookies; and similar baked products); chewing gum; confections and frostings; dressings for salads; frozen dairy desserts and mixes; fruit spreads; gelatins, puddings and fillings; hard and soft candy; peanut spread; sweet sauces, toppings, and syrups.

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Dated: June 6, 1994.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 94–17923 Filed 7–21–94; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 343

[Docket No. 94N–0255]

Over-the-Counter Marketing of Internal Analgesic, Antipyretic, and Antirheumatic Drug Products; Background Document for Advisory Committee Meeting; Availability; Establishment of a Public Docket and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of background document; establishment of a public docket and request for comments.

SUMMARY: The Food and Drug Administration is announcing the availability of a background document for the joint meeting of the Nonprescription Drugs Advisory Committee and the Arthritis Advisory Committee on effectiveness data requirements and labeling for over-the-counter (OTC) marketing of internal analgesic, antipyretic and antirheumatic drug products scheduled for September 8 and 9, 1994. The background information is being made available to ensure that all interested parties are aware of the issues that are the subject of the committee discussion. FDA is also announcing that it is establishing a public docket for comments, views, and other information submitted to the agency on these subjects from interested persons.

DATES: Submit written comments by August 15, 1994, in order for written comments to be considered for discussion at the September 8 and 9, 1994, advisory committee meeting.

ADDRESSES: Submit written comments or relevant data and requests for single copies of the background document to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Comments and requests should be identified with the docket number found in the brackets in the heading of this document. Send two self-addressed adhesive labels to assist the branch in processing your requests. Three copies of written comments should be submitted, except that individuals may submit one copy. The background document and received comments are available for public examination at the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 11, 1994 (59 FR 35375), FDA announced that a forthcoming joint meeting of the Nonprescription Drugs Advisory Committee and the Arthritis Advisory Committee on effectiveness data requirements and labeling for over-the-counter (OTC) marketing of internal analgesic, antipyretic and antirheumatic drug products will be held on September 8 and 9, 1994. FDA is holding this meeting to discuss:

(1) Data requirements to support specific types of indications for OTC analgesic drug products;

(2) Recommendations for labeling indications for OTC analgesics; and

(3) The current state of scientific knowledge in the areas of pain receptors, mechanism(s) of pain perception, and the basis for response to analgesic drug classes.

The purpose of this meeting is to address specific topics and questions contained in the background document that could result in future rulemaking.

FDA has established public docket No. 94N–0255 to enable interested persons to submit comments or other relevant data on the background document.

Dated: July 15, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–17811 Filed 7–21–94; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Melatonin Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Wildlife Laboratories, Inc. The NADA provides for the subcutaneous use of melatonin implant in healthy male and female kit and adult female mink to accelerate the fur priming cycle.

EFFECTIVE DATE: July 22, 1994.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.