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Food and Drug Administration
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★ First Match

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

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'This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Nonprescription Drugs Advisory Committee with Representation from the Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: The committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

Date and Time: The meeting will be held on May 13, 1997, 8:30 a.m. to 5 p.m. An open public hearing portion is scheduled from 8:30 a.m. to 9:30 a.m.

Location: Holiday Inn--Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Andrea Neal or Angie Whitacre, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear presentations and discuss data submitted regarding the switch from prescription to over-the-counter status of new drug application (NDA) 16-640/S072, Questran(R) Powder (cholestyramine resin) and NDA 19-669/S020, Questran(R) Light (cholestyramine resin with aspartame), Bristol Myers Squibb, for the reduction of elevated serum cholesterol.

Procedure: The meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to

the contact person by May 8, 1997. Those desiring to make formal presentations should notify the contact person before May 8, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 17, 1997.

Michael A. Friedman,
Deputy Commissioner for Operations.
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