nausea during pregnancy. The original formulation of the antinauseant included dicyclomine hydrochloride, pyroxidine hydrochloride, and doxylamine succinate. The drug was reviewed in the agency's Drug Efficacy Study Implementation program, in which FDA concluded that dicyclomine hydrochloride did not contribute to the effectiveness of the other two ingredients in Bendectin tablets. Therefore, the drug product was reformulated in 1976 to include only pyroxidine hydrochloride, 10 mg, and doxylamine succinate, 10 mg.

On June 9, 1983, Merrell Dow, HMR's predecessor in interest, withdrew Bendectin tablets from sale in the United States and worldwide. Other companies have continued to market this product in other areas of the world. To FDA, to the press, and in letters to customers using Bendectin tablets, Merrell Dow, in explaining its decision, stated that the withdrawal of the drug product was due to nonmedical reasons, noting significant adverse publicity and the burdens of litigation. At the same time, Merrell Dow asserted its view that ''available medical evidence does not demonstrate a cause and effect relationship between the use of Bendectin and birth defects.'' In an FDA Talk Paper issued on the day Bendectin was withdrawn from sale, the agency stated that Merrell Dow's decision was ''independent'' of action by FDA. HMR and predecessors in interest to HMR have continually maintained that the withdrawal of Bendectin tablets was for reasons other than safety or effectiveness.

On June 24, 1992, Townley & Updike, on behalf of Pharmaceutical Development and Licensing, Inc., submitted a citizen petition under 21 CFR 10.30 (Docket No. 92P–0274/CP1) regarding the status of Bendectin. A similar citizen petition was filed by Cato Research on behalf of Duchesnay Inc., on October 20, 1997 (Docket No. 97P–0437/CP1). Both petitions request that the agency determine whether Bendectin was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, relist the drug in the Orange Book.

Under § 314.161, the relevant inquiry is whether the manufacturer withdrew the drug from the market for reasons of safety or effectiveness. Where, as here, a substantial amount of time has elapsed since a drug was withdrawn from the market, the agency's inquiry considers not only the reasons the manufacturer initially ceased marketing the product, but also any relevant information that has become available since the market withdrawal. Because a finding that a product was not withdrawn for safety or effectiveness reasons will permit the approval of ANDA's for the drug, the agency considers all relevant information, not just information available at the time of the initial withdrawal, to determine whether a drug is no longer on the market due to safety or effectiveness concerns.

The agency's review of the withdrawal of Bendectin from the market has considered the sponsor's explanation of the basis for the withdrawal of the product in 1983 and information available to the agency regarding safety or effectiveness concerns for Bendectin. As noted previously, the sponsor has consistently maintained that it withdrew Bendectin from the market for reasons other than safety or effectiveness. The agency has reviewed information submitted with the petitions, published studies, U.S. and foreign adverse event reports, and FDA records. The current evidence supports the conclusion that Bendectin was not withdrawn from the market for reasons of safety or effectiveness.

Doxylamine succinate is an active ingredient in several over-the-counter (OTC) antihistamines and sleep aids. The labeling of these OTC products bears statements that pregnant women should seek the advice of a health professional before using the products or that the products should not be taken by pregnant women. These statements do not contradict FDA's present determination because the combination product pyroxidine hydrochloride, 10 mg, and doxylamine succinate, 10 mg, is a prescription drug product. As with all prescription drug products that are being considered for use in a pregnant woman, a health professional may appropriately assess the risks and benefits of pyroxidine hydrochloride and doxylamine succinate for its intended use.

Pyroxidine hydrochloride is also known as vitamin B_6. As an individual product, it is readily available to U.S. consumers without the requirement of a prescription.

The agency has determined under § 314.161 that Bendectin was not withdrawn from the market for reasons of safety or effectiveness. Accordingly, the agency will list Bendectin tablets in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to the combination product pyroxidine hydrochloride, 10 mg, and doxylamine succinate, 10 mg, tablets may be approved by the agency.

Dated: July 28, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–20362 Filed 8–6–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee); Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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: Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee).

General Function of the Committee: To advise the Secretary and the Assistant Secretary for Health concerning its oversight of the conduct of the ranch hand study by the U.S. Air Force and to provide scientific oversight of the Department of Veterans Affairs Army Chemical Corps Vietnam Veterans Health Study, and other studies in which the Secretary or the Assistant Secretary for Health believes involvement by the committee is desirable.

Date and Time: The meeting will be held on August 26 and 27, 1999, 8:30 a.m. to 5 p.m.

Location: Parklawn Bldg., 5600 Fishers Lane, conference room K, Rockville, MD.

Contact Person: Ronald F. Coene, Food and Drug Administration, 5600 Fishers Lane, rm. 16–53, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12560. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will review the draft report of the Air Force Health Study–Cycle 5.

Procedure: 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 August 6, 1999. Oral presentations from the public will be scheduled on August 27, 1999, between approximately 11 a.m. to 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 6, 1999, 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: July 30, 1999

Linda A. Suydam,

Senior Associate Commissioner

[FR Doc. 99–20365 Filed 8–6–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–98–6000]

Memorandum of Understanding Between the Food and Drug Administration and States of Illinois

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a Memorandum of Understanding (MOU) between FDA and the State of Illinois Department of Nuclear Safety. The purpose of the MOU is to authorize the State to implement a State certification program under the Mammography Quality Standards Act.

DATES: The agreement became effective August 3, 1998.

FOR FURTHER INFORMATION CONTACT: Lireka P. Joseph, Center for Devices and Radiological Health (HFZ–200), Food and Drug Administration, 2094 Gaither Rd., Gaithersburg, MD 20850, 301–443–2845. **SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

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