DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 80N–0280]

RIN 0905–AA06

Vaginal Contraceptive Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would require manufacturers of over-the-counter (OTC) vaginal contraceptive drug products to obtain approved applications for marketing of their products. The agency is taking this action because the effectiveness of these products is dependent upon the final formulation. Therefore, each product must be tested in appropriate clinical trials under actual conditions of use. This action will ensure the maximum effectiveness of OTC vaginal contraceptive drug products for consumers. This proposed rulemaking does not affect the current marketing status of OTC vaginal contraceptives. Thus, persons who are using or wish to use these drug products may do so. However, on the effective date of a final regulation, an OTC vaginal contraceptive drug product that is not the subject of an approved application would be regarded as a new drug and subject to regulatory action. Manufacturers will have adequate time to conduct studies and submit applications before the effective date of the final rule. Under existing procedures, there is a minimum of 26 months from today before a final rule could become effective. Despite this timeframe, manufacturers are urged to contact the agency regarding submission of their application as soon as possible. OTC contraceptives that are marketed for use with or as part of a device, e.g., diaphragm, condom, or contraceptive cervical cap will not be addressed in this document but will be addressed in a separate publication. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products, public comments on an advance notice of proposed rulemaking that was based on those recommendations, and evolving new information about these products. This proposal is part of the ongoing review of OTC drug products conducted by FDA. While this document does not address the use of vaginal contraceptive drug products for prophylaxis against human immunodeficiency virus (HIV) and other sexually transmitted diseases (STD's), FDA is aware of literature reports and other data relative to such use. FDA strongly encourages manufacturers to evaluate these products for use in the prevention of infectious diseases.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by June 5, 1995. New data by February 5, 1996. Comments on the new data by April 3, 1996. Written comments on the agency's economic impact determination by June 5, 1995.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 12, 1980 (45 FR 82014), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC vaginal contraceptive drug products, together with the recommendations of the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in OTC vaginal contraceptive drug products. Interested persons were invited to submit comments by March 12, 1981. Reply comments in response to comments filed in the initial comment period could be submitted by April 13, 1981.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information.

In response to the advance notice of proposed rulemaking, six drug manufacturers, two governmental agencies, two reproductive health groups, one trade association, one chemical company, and one consumer submitted comments. Copies of the comments received are on public display in the Dockets Management Branch.

The advance notice of proposed rulemaking, which was published in the **Federal Register** on December 12, 1980, was designated as a ''proposed rule'' in order to conform to terminology used in the OTC drug review regulations § 330.10. Similarly, the present document is designated in the OTC drug review regulations as a tentative final rule. Its legal status, however, is that of a proposed rule. To establish new § 310.535 by this notice of proposed rulemaking, FDA responds to public comment and states, for the first time, its position on OTC vaginal contraceptive drug products. Final agency action on this matter will occur with the publication, at a future date, of a final rule relating to OTC vaginal contraceptive drug products.

This proposal constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC vaginal contraceptive drug products as modified on the basis of the comments received, the agency's independent evaluation of the Panel's report, and evolving new information on these products. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them.

The OTC drug procedural regulations (§ 330.10) provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA is no longer using the terms ''Category I'' (generally recognized as safe and effective and not misbranded), ''Category II'' (not generally recognized as safe and effective or misbranded), and ''Category III'' (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage. In place of Category I, the term ''monograph conditions'' is used; in place of Category II or III, the term ''nonmonograph conditions'' is used.

Based on all information available to date, the agency has tentatively concluded that any OTC vaginal contraceptive drug product should be regarded as a new drug and be subject to regulatory action unless it is the