1997 Federal Register (Vol 62) January - December
November
Vol. 62 No. 223 Wednesday, November 19,1997
Food and Drug Administration
Human drugs: Antifungal products (OTC), etc.; administrative records reopening, 61710

★ First Match

PROPOSED RULES

Human drugs: Antifungal products (OTC), etc.; administrative records reopening, 61710

Vol. 62 No. 223 Wednesday, November 19, 1997 p 61710 (Proposed Rul 1/186

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CF'R Part:; 333, 347, and 348

[Docket Nos. 80N-0476, 78N-0301, 78N-0021, and 75N-0183]
RIN 0910-AA01

Antifungal Drug Products for Over-the-Counter Human Use; External Analgesic Drug Products for Over-the-Counter Human Use; Skin Protecrant Drug Products for Over-the-Counter Human Use; and Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Reopening of Administrative Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of administrative records.
t

SUMMARY: The Food and Drug Administration (FDA) is announcing the reopening of the administrative records for four rulemakings to include safety and effectiveness data on over-the-counter (OTC) vaginal douche drug product: ingredients that were previously considered in the advance

---- page << 61711>> ----

notice of proposed rulemaking for OTC vaginal drug products. The agency is reopening the following rulemakings for consideration of data on vaginal douche drug products: (1) Antifungal drug products, (2) OTC external analgesic drug products (3) OTC skin protectant drug products and (4) OTC topical antimicrobial drug products. This action is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written comments by February 17, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch

(HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Helen Cothran, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 13, 1983 (48 FR 46694), FDA published under 21 CFR 330.10(a)(6), an advance notice of proposed rulemaking to establish a monograph for OTC vaginal 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 drug products. In its report, the Panel recommended Category I (i.e., safe and effective) status for 1 to 3 percent potassium sorbate and 0.15 to 0.3 percent povidone-iodine as a douche for the relief of minor vaginal itching, irritation, and soreness (48 FR 46694 at 46704 to 46706). The Panel also recommended the following ingredients as Category I in a douche formulation to remove vaginal discharge and vaginal secretions, for a mild detergent action, and to thin out vaginal mucus discharge: 0.002 percent dioctyl sodium sulfosuccinate (docusate sodium), 0.0176 percent nonoxynol 9, 0.088 percent octoxynol 9, and 0.01 to 0.02 percent sodium lauryl sulfate (48 FR 46706 to 46707). In the preamble to the Panel's report (48 FR 46694 to 46695), the agency did not allow the marketing of potassium sorbate for relief of minor vaginal irritation because it was cons dered a new drug (had not been marketed for a material time and extent).

In the Federal Register of February 3, 1994 (59 FR 5226), the agency issued a notice to withdraw the advance notice of proposed rulemaking of October 13, 1983. This action was taken in part because the agency determined that some of the Panel's recommended labeling indications related to cosmetic claims and not drug claims. The agency also stated that the intended use of a product will be considered in determining whether it is a cosmetic, a drug, or both (59 FR 5226 at 5231). In addition, recommended labeling indications and ingredients used for minor irritation, itching, or soreness are not unique to the vaginal area and are already being considered in other OTC drug rulemakings (e.g., antifungal, antimicrobial, and external analgesic). Therefore, the agency stated that those ingredients and claims would be considered in those other rulemakings, as appropriate.

II. Recent Developments

In the Federal Register of March 27, 1997 (62 FR 14683), the agency announced that its Nonprescription Drugs Advisory Committee (NDAC) would hold a public meeting on April 15, 1997, to discuss a possible association between vaginal douching and adverse consequences. The notice stated that FDA is aware of a number of case-control epidemiologic studies in the literature that suggest a possible association between vaginal douching and several conditions, such as pelvic inflammatory disease, ectopic pregnancy , and cervical cancer (Ref. 1). At the April 15, 1997, meeting, NDAC members were joined by representatives from two other FDA advisory committees, Reproductive Health Drugs and Anti-infective Drugs, as well as representatives from the Center for Food Safety and Applied Nutrition and the Center for

Devices and Radiological Health. The Committees discussed issues relating to behavioral, epidemiological, and microbiological aspects of vaginal douching. Committee members felt that there was a suggestive association between vaginal douching and ectopic pregnancy and pelvic inflammatory disease, but that more data and further research were needed to support such an association. Some members stated that a possible association between douching and tubal infertility also needed more investigation. The Committees did not find any evidence of a relationship between vaginal douching and cervical carcinoma. Some members expressed concern that certain individuals who douche, e.g., those with sexually transmitted diseases or multiple sexual partners, may be at increased risk for ectopic pregnancy, tubal disease, or tubal infertility. The Committees were also concerned about the risks and benefits/efficacy of vaginal douche products. The Committee members stressed that labeling for these products should be easy to read and understand, and should provide consistent information across the broad product class. The Committees encouraged the use of educational programs for both consumers and health care providers as a way to expand the public's knowledge about use of these products (Ref. 2).

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from D. Bowen, FDA, to R.W. Soller, Nonprescription Drug Manufacturers Association, coded LET 105, Docket No. 75N-0183, Dockets Management Branch.

2. Comment No. TR1, Docket No. 80N-0476, Dockets Management Branch.

IV. Reopening of the Administrative Records

Because the issues concerning the safety of vaginal douching also have an impact on the agency's review of the safety and effectiveness of all OTC vaginal douche drug products, the agency is reopening the administrative records for the rulemakings for OTC antifungal drug products (Docket No. 80N-0476), (2) OTC external analgesic drug products (Docket No. 78N-0301), (3) OTC skin protectant drug products (Docket No. 78N-0021), and (4) OTC topical antimicrobial drug products (Docket No. 75N-0183). This action is to specifically allow for submission of data on the issues raised at the April 15, 1997, meeting. The agency also requests safety and effectiveness data on the vaginal douche drug product ingredients that were discussed at that meeting.

Interested persons may submit comments on OTC vaginal douche drug products to the applicable docket number(s) based on the ingredient's labeling claim(s), intended use, or mechanism/mode of action. For example, data on povidone-iodine for the relief of minor vaginal itching and irritation may be submitted to the external analgesic rulemaking, but if relief of itching is due to an antifungal effect, i.e., killing the fungus, data should be submitted to the antifungal rulemaking . Likewise, if data support the use of nonoxynol 9 for the relief of minor vaginal itching and irritation because of an antimicrobial action, data should be submitted to the antimicrobial rulemaking. Interested

---- page 61712 ----

persons should determine the appropriate rulemaking to which data should be submitted. Comments on other vaginal drug products or issues

should not be submitted at this time.

Submit written comments on or before February 17, 1998 to the Dockets Management Branch (address above). Three copies of any comments are to be submitted, except that individuals may submit one copy. If comments could be submitted to several dockets, they may be submitted to one docket and cross-referenced in the other docket(s). All comments are to be identified with the appropriate docket number(s) found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 12, 1997.
William K. Hubbard,
Associate Commissioner for Policy Coordination.
[FR Doc. 97-30410 Filed 11-18-97; 8:45 am]
BILLING CODE 4160-01-F

The Contents entry for this article reads as follows:

Human drugs:
Antifungal products (OTC), etc.; administrative records reopening, 61710