for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final rule for OTC vaginal contraceptive drug products, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on April 3, 1996. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final rule for OTC vaginal contraceptive drug products is published in the **Federal Register**, unless the Commissioner finds that good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 310 be amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

2. Section 310.535 is added to subpart E to read as follows:

§ 310.535 Drug products containing active ingredients offered over-the-counter (OTC) for human use as a vaginal contraceptive.

(a) Dodecaethyleneglycol monolaurate, laureth 10S, methoxypolyoxyethyleneglycol 550 laurate, nonoxynol 9, octoxynol 9, phenylmercuric acetate, and phenylmercuric nitrate have been present as ingredients in OTC vaginal contraceptive drug products. The evidence currently available shows that clinical studies in humans are necessary to establish the effectiveness of nonoxynol 9 and octoxynol 9 in final formulation for use in OTC vaginal contraceptive drug products. There are inadequate data to establish the safety and effectiveness of any other ingredients offered for use as OTC vaginal contraceptive drug products.

(b) Any drug product that is labeled, represented, or promoted for OTC use as a vaginal contraceptive is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act), for which an approved application or abbreviated application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application or abbreviated new drug application, such product is also misbranded under section 502 of the act.

(c) Clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted for OTC use as a vaginal contraceptive is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) After (date 12 months after date of publication in the **Federal Register** of the final rule), any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

Dated: January 10, 1995.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

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