Appendix A to Part 145—Compilation of Commission Records Available to the Public.

6. In Appendix A remove paragraph (b)(1) and redesignate paragraphs (b)(2) through (b)(13) as (b)(1) through (b)(12), respectively; and in paragraph (g) of Appendix A remove the phrase ''from the Division of Trading and Markets, Commodity Futures Trading Commission, 300 South Riverside Plaza, suite 1600 North, Chicago, Illinois 60606 or''.

7. Amend Appendix B to Part 145 by revising paragraph (a)(3) to read as follows:

Appendix B to Part 145—Schedule of Fees.

(a) * * *

(3) The Commission uses a variety of computer systems to support its operations and store records. Older systems of records, particularly systems involving large numbers of records, are maintained on a mainframe computer. More recently, systems have been developed using small, inexpensive, shared computer systems to store records. Systems of use in particular programmatic and administrative operations may also store records on the workstation computers assigned to particular staff members. For searches of records stored on the Commission's mainframe computer, the use of computer processing time will be charged at $456.47 for each hour, $7.61 for each minute, and $0.1268 for each second of computer processing time indicated by the job accounting log printed with each search. When searches require the expertise of a computer specialist, staff time for programming and performing searches will be charged at $32.00 per hour. For searches of records stored on personal computers used as workstations by Commission staff and shared access network servers, the computer processing time is included in the search time for the staff member using that workstation as set forth in the other subsections of Appendix B, section (a).

* * * * *

PART 147—OPEN COMMISSION MEETINGS

8. The authority for part 147 continues to read:

Authority: Sec. 3(a), Pub. L. 94–409, 90 Stat. 1241 (5 U.S.C. 552b); sec. 101(a)(11), Pub. L. 93–463, 88 Stat. 1391 (7 U.S.C. 4a(j)(Supp. V, 1975)), unless otherwise noted.

§147.3 [Amended]

9. In § 147.3 make the following changes:

a. Remove the introductory text of paragraph (b)(4)(i).

b. In paragraphs (b)(4)(i)(A) (*2*) and (*5*) remove the following phrase: ''*Provided*, The procedure set forth in 17 CFR 1.10(g) is followed:''.

c. In paragraphs (b)(4)(i)(A) (*3*) and (*4*) remove the following phrase: '', provided, the procedure set forth in § 1.10(g) of this chapter is followed''.

d. In paragraphs (b)(4)(i)(A) (*6*) and (*7*) remove the following phrase: '', if the procedure set forth in § 1.10(g) of this chapter is followed''.

e. In paragraph (b)(4)(i)(A)(*8*) remove the following phrase: ''provided the procedure set forth in § 31.13(m) of this chapter is followed''.

Issued by the Commission.

Dated: December 11, 1996.

Jean A. Webb,

Secretary of the Commission, Commodity Futures Trading Commission.

[FR Doc. 96–31930 Filed 12–18–96; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 351

[Docket No. 80N–0280]

RIN 0910–AA01

Vaginal Contraceptive Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is announcing the reopening of the administrative record for the proposed rulemaking for over-the-counter (OTC) vaginal contraceptive drug products to allow for comment on matters considered at the November 22, 1996, joint meeting of the Nonprescription Drugs, Reproductive Health Drugs, Anti-Infective Drugs, and Antiviral Drugs Advisory Committees. That meeting is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit comments regarding matters discussed at the November 22, 1996, advisory committee by March 3, 1997. The administrative record will remain open until March 3, 1997.

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: Gloria Chang, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2245.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 12, 1980 (45 FR 82014), FDA published 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). The Panel recommended that the spermicidal ingredients nonoxynol 9 and octoxynol 9 be considered generally recognized as safe and effective (45 FR 82014 at 82028 to 82030 and 82047). The Panel also recommended final formulation in vitro testing as an adequate method to determine effectiveness (45 FR 82014 at 82047).

In the Federal Register of February 3, 1995 (60 FR 6892), the agency published a proposed rule for OTC vaginal contraceptive drug products. This proposal would require manufacturers to obtain approved applications for marketing of OTC vaginal contraceptive drug products. The agency stated that although nonoxynol 9 and octoxynol 9 kill sperm in vitro and in vivo, the spermicidal activity and resulting effectiveness of these contraceptive ingredients cannot be considered separately from a product's vehicle. Thus, clinical studies are necessary to establish the effectiveness of the spermicide's final formulation when used in humans. The agency also announced the availability of a guidance document that is intended to help manufacturers of vaginal contraceptive drug products develop data in support of applications (60 FR 6892 at 6893). The administrative record for this proposed rule closed on April 3, 1996.

In response to the proposed rule, 13 professional associations, 1 health professional, 1 trade association, 10 public health groups, 4 manufacturers, 1 consumer, and 1 research laboratory submitted comments. The majority of the comments objected to the agency's proposal to require approved applications for marketing of OTC vaginal contraceptive drug products. Copies of the comments received are on public display in the Dockets Management Branch (address above).

On September 24, 1996, FDA met with the Nonprescription Drug

Manufacturers Association (NDMA) (Ref. 1) to provide industry an opportunity to discuss its position on FDA's proposed rule for OTC vaginal contraceptive drug products. NDMA opposed the requirement of applications for these products and requested that FDA reconsider its position to reject monograph standards for OTC vaginal spermicides.

In the Federal Register of October 30, 1996 (61 FR 55990), FDA announced a joint meeting of the Nonprescription Drugs, Reproductive Health Drugs, Anti-Infective Drugs, and Antiviral Drugs Advisory Committees. The meeting took place on November 20–22, 1996, at the Holiday Inn-Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD. On November 22, 1996, the committees discussed proposals and guidance for clinical efficacy studies on marketed OTC vaginal spermicides. Issues for discussion included the type of data and quality of both in vitro and in vivo data needed to support and ensure spermicidal efficacy in final formulation.

Because the issues have a direct impact on FDA's rulemaking on OTC vaginal contraceptive drug products, the agency is reopening the administrative record to specifically allow for comments on the matters discussed at the November 22, 1996, meeting. Transcripts of the November 22, 1996, meeting may be requested (by mail or fax) from the Freedom of Information Staff (HFI–35), 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, 301–443–6310; or FAX 301–443–1726. Requests should specify date of meeting, name of committee, and a description of document(s) requested. The agency requests data and information regarding clinical efficacy studies, and in vivo and in vitro data needed to support and ensure spermicidal efficacy in final formulation. Any individual or group may, on or before March 3, 1997, submit to the Dockets Management Branch (address above), comments and data specifically limited and relevant to the matters discussed at the November 22, 1996, meeting. Two copies of any comments are to be submitted, except that individuals may submit one copy. All comments are to be identified with the docket number found in brackets in the heading of this document. The administrative record will remain open until March 3, 1997.

Reference

(1) Minutes of meeting between FDA and NDMA, September 24, 1996, coded MM1, Docket No. 80N–0280, Dockets Management Branch.

Dated: December 3, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32273 Filed 12–18–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 812

[Docket No. 96N–0299]

Investigational Device Exemptions; Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing procedures to allow for the treatment use of investigational devices. These procedures are intended to facilitate the availability of promising new therapeutic and diagnostic devices to desperately ill patients as early in the device development process as possible, i.e., before general marketing begins, and to obtain additional data on the device's safety and effectiveness. These procedures would apply to patients with serious or immediately life-threatening diseases or conditions for which no comparable or satisfactory alternative device, drug, or other therapy exists.

DATES: Submit written comments by March 19, 1997. Written comments on the information collection requirements should be submitted by January 21, 1997. FDA proposes that any final rule that may issue based on this proposal become effective 30 days after date of publication of the final rule.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Joanne R. Less, Office of Device Evaluation (HFZ–403), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of May 22, 1987 (52 FR 19466), FDA published a final rule that codified procedures authorizing the treatment use of investigational new drugs (IND's) (hereinafter referred to as the treatment IND regulation). In publishing the treatment IND regulation, FDA was responding to an increased demand from patients as well as from health professionals to permit broader availability of investigational drugs to treat serious diseases for which there were no satisfactory alternative treatments. For similar reasons, FDA is now proposing to amend its Investigational Device Exemption (IDE) regulations (part 812 (21 CFR part 812)). With minor exceptions, the proposed rule parallels the regulation for treatment use of investigational new drugs and extends those provisions to cover the treatment use of investigational devices, including diagnostic devices. The proposed rule is intended to facilitate the availability of promising new devices to patients as early in the device development process as possible while safeguarding against commercialization of the devices and ensuring the integrity of controlled clinical trials.

II. Summary of the Proposed Rule

The proposed rule amends part 812 by adding proposed § 812.36, which parallels the IND treatment use provisions contained in 21 CFR 312.34 and 312.35. The proposed rule consists of the following provisions.

A. Purpose

Proposed § 812.36(a) provides for the treatment use of investigational devices in order to facilitate the availability of promising new devices to desperately ill patients as early in the device development process as possible, before general marketing begins, and to obtain additional data on the device's safety and effectiveness.

B. Criteria

Proposed § 812.36(b) specifies that treatment use of an investigational device would only be considered when the following criteria are satisfied: (1) The device is intended to treat or diagnose a serious or immediately life-threatening disease or condition; (2) there is no comparable or satisfactory alternative device or other therapy available to treat or diagnose that stage of the disease or condition in the intended patient population; (3) the device is under investigation in a controlled clinical trial under an approved IDE, or all clinical trials have been completed; and (4) the sponsor of the controlled clinical trial is pursuing marketing approval/clearance of the