Concentrate (Human)" and "Single Donor Plasma (Human), Platelet Rich" as follows:

§ 610.53 Dating periods for specific products.

(a) * * *

Platelet Concentrate (Human). (a) 72 hours from time of collection of source blood, provided labeling recommends storage at 20° to 24° C or, (b) 48 hours from time of collection of source blood, provided labeling recommends storage at 1° to 6° C. Section 610.51 does not apply.

* * * * *

Single Donor Plasma (Human), Platelet Rich. (a) 72 hours from time of collection of source blood, provided labeling recommends storage at 20° to 24° C or, (b) 48 hours from time of collection of source blood, provided labeling recommends storage at 1° to 6° C. Section 610.51 does not apply.

* * * * *

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

3. In Part 640:

a. Section 640.20(a) is amended by revising the last sentence to read as follows:

§ 640.20 Platelet concentrate (Human).

(a) * * * The product is defined as platelets collected from one unit of blood and resuspended in an appropriate volume of original plasma, as prescribed in § 640.24(d).

* * * * *

b. Section 640.24 is amended by revising paragraph (d), to read as follows:

§ 640.24 Processing.

* * * * *

(d) The volume of original plasma used for resuspension of the platelets shall be determined by the maintenance of a pH of not less than 6.0 during the storage period. The pH shall be measured on a sample of platelet concentrate which has been stored for the maximum dating period at the selected storage temperature. One of the following storage temperatures shall be used continuously:

(1) 20° to 24° C.

(2) 1° to 6° C.

* * * * *

c. Section 640.25 is amended by revising paragraphs (a) and (b), to read as follows:

§ 640.25 General requirements.

(a) *Storage.* Immediately after resuspension, Platelet Concentrate (Human) shall be placed in storage at the selected temperature range. If stored at 20° to 24° C, a continuous gentle agitation of the platelet concentrate shall be maintained throughout the storage period. Agitation is optional if stored at a temperature between 1° and 6° C.

(b) *Quality control testing.* Each month four units prepared from different donors shall be tested at the end of the storage period as follows:

(1) Platelet count.

(2) pH of not less than 6.0 measured at the storage temperature of the unit.

(3) Measurement of actual plasma volume.

(4) If the results of the quality control testing indicate that the product does not meet the prescribed requirements, immediate corrective action shall be taken and a record maintained of such action.

* * * * *

d. Section 640.26 is amended by revising paragraph (e), to read as follows:

§ 640.26 Labeling.

* * * * *

(e) The ABO and Rh blood group designations of the source blood.

* * * * *

Effective dates. This regulation becomes effective November 29, 1982. Labeling requirements shall become effective April 29, 1983. On or after April 29, 1983, no person may initially introduce or initially deliver for introduction into interstate commerce any licensed biological product to which the regulations apply, unless the product's labeling complies with the requirements set forth in the regulations.

(Secs. 201, 502, 701, 52 Stat. 1041–1042 as amended, 1050–1051 as amended, 1055–1056 as amended (21 U.S.C. 321, 352, 371); sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262))

Dated: October 7, 1982.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-29729 Filed 10-28-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 884

[Docket No. 81P-0306]

Schmid Laboratories, Inc.; Reclassification of Condom With Spermicidal Lubricant

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation that codifies the reclassification of the condom with spermicidal lubricant (nonoxynol-9) from class III (premarket approval) into class II (performance standards). FDA also is announcing that it issued an order in the form of a letter to a petitioner reclassifying the device. The effect of reclassifying a device into class II is to require that the device meet the general controls applicable to all devices and comply with the requirements of any performance standard applicable to the device. FDA reclassified this device in response to a petition from Schmid Laboratories, Inc., Little Falls, NJ 07424.

EFFECTIVE DATES: The reclassification was effective on August 9, 1982. This rule becomes effective November 29, 1982.

FOR FURTHER INFORMATION CONTACT: Lillian Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION: On August 28, 1981, Schmid Laboratories, Inc., Little Falls, NJ 07424, submitted to FDA under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)), a petition requesting that a new device with the brand name "Condom with Spermicidal Lubricant (nonoxynol-9)" be reclassified from class III into class II. The device was classified by statute into class III because it was not in commercial distribution before enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) (see 21 U.S.C. 360c(f)(1)), nor is it substantially equivalent to another device that was in commercial distribution before the date of enactment or to another device that was classified by statute into class III and subsequently reclassified.

FDA referred the petition to the Obstetrics-Gynecology Device Section of the Obstetrics-Gynecology and Radiology Devices Panel (the Section) for a recommendation. On September 28, 1981, the Section reviewed the petition and recommended that FDA reclassify the device into class II, provided the labeling bear the following specific contraceptive effectiveness cautionary provision:

> The condom with spermicidal lubricant is a contraceptive which combines a latex condom and a lubricant containing nonoxynol-9, a spermicide. Evidence of added contraceptive effectiveness has not been established with the addition of a spermicidal preparation to the condom.

The recommendation was based on the Section's belief that although general

controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device, sufficient scientific and medical data exist to establish a performance standard to provide such assurance.

In a notice published in the **Federal Register** of April 30, 1982 (47 FR 18670), FDA announced the Section's recommendation that the condom with spermicidal lubricant be reclassified from class III into class II, provided the labeling bear the contraceptive effectiveness cautionary statement. FDA tentatively concluded that the statement could not provide a basis for reclassification because, under section 513(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(3)) and § 860.134 (21 CFR 860.134), a device may not be reclassified absent a showing, by valid scientific evidence, that the reclassification requested will provide reasonable assurance of the effectiveness, as well as the safety, of the device. FDA suggested, however, that the following modification of the Section's proposed labeling would be both lawful and appropriate:

> The presence of a spermicide in this product may be helpful in decreasing the risk of pregnancy should the condom fail or be misused.

The notice provided a period of 30 days for interested persons to submit to FDA written comments on FDA's tentative conclusions and the Section's recommendation that the condom with spermicidal lubricant be reclassified from class III into class II.

FDA received three comments on the notice. After reviewing the petition, the Section's recommendation, and the comments, FDA, in accordance with section 513(f)(2)(C)(i) of the act and § 860.134(b)(6) of the regulations, approved the petition and, by order dated August 9, 1982, and sent to the petitioner, reclassified the device from class III into class II, provided the device labeling bears the specific contraceptive effectiveness cautionary provision set forth below:

> This product combines a latex condom and a spermicidal lubricant. The spermicide, nonoxynol-9, reduces the number of active sperm, thereby decreasing the risk of pregnancy if you lose your erection before withdrawal and some semen spill outside the condom. However, the extent of decreased risk has not been established. This condom should not be used as a substitute for the combined use of a vaginal spermicide and a condom.

The order requires the provision to appear prominently and conspicuously on the principal display panel, as defined in 21 CFR 801.60, of any package of the product and on any insert included in the package of the product. The order also requires the provision to appear prominently and conspicuously on any condom with spermicidal lubricant that is individually labeled with representations that it bears or contains a spermicidal lubricant. In addition, the order requires labeling for the condom with spermicidal lubricant to bear the expiration date of the spermicidal agent, along with this statement, "The expiration date on this product applies only to the spermicidal agent in it." The data submitted by Schmid establish that the stability of the spermicidal agent in the condom with spermicidal lubricant is 44 months.

The reasons and basis for the reclassification of the device from class III into class II, as well as the reasons and the basis for the conditions of that reclassification, are set forth in the order. The order also contains FDA's responses to the comments received on the April 30, 1982 notice. The order and all the references cited in it are on public file in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, where they may be seen by interested persons, between 9 a.m. and 4 p.m., Monday through Friday.

As required by § 860.134(b)(7) of the regulations, FDA is announcing the reclassification of a generic type of device FDA calls a condom with spermicidal lubricant from class III into class II. In addition, FDA is issuing a final regulation that codifies in § 884.5310 (21 CFR 884.5310) the reclassification of the device. FDA advises that any device it determines to be substantially equivalent to the condom with spermicidal lubricant also will be reclassified from class III into class II. FDA further advises that the condom with spermicidal lubricant that has been reclassified into class II has been reclassified only insofar as its labeling bears the contraceptive effectiveness cautionary provision and expiration date statement set out above.

After considering the economic consequences of approving this reclassification, FDA certifies that this final rule requires neither a regulatory impact analysis, as specified in Executive Order 12291, nor a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). Approval of this petition will not have a significant economic impact on a substantial number of small entities. The petitioner, and future manufacturers of devices that are determined to be substantially equivalent to the condom with spermicidal lubricant, will be relieved of the costs of complying with the premarket approval requirements in section 515 of the act; whereas if the device had remained classified in class III, each manufacturer of the device would have been required to submit to FDA for its approval an application for premarket approval. There are no offsetting costs that the petitioner or other manufacturers would incur from reclassification into class II. The magnitude of the economic savings from approval of this petition depends on the extent of premarket approval studies that the petitioner would have conducted and the number of future competitors satisfying the same requirements. Neither of these parameters can be reliably calculated to permit quantification of the economic savings.

List of Subjects in 21 CFR Part 884

Medical devices, Obstetrical and gynecological devices.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 884 is amended in Subpart F by adding new § 884.5310, to read as follows:

§ 884.5310 Condom with spermicidal lubricant.

(a) *Identification.* A condom with spermicidal lubricant is a sheath which completely covers the penis with a closely fitting membrane with a lubricant that contains a spermicidal agent, nonoxynol–9. This condom is used for contraceptive and prophylactic purposes (preventing transmission of venereal disease).

(b) *Classification.* Class II (performance standards).

Effective dates. This reclassification was effective August 9, 1982. This rule becomes effective November 29, 1982.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)))

Dated: October 7, 1982.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 82–29593 Filed 10–28–82; 8:45 am]

BILLING CODE 4160–01–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 256

[SW-9-FRL 2235-6]

Approval of the Guam Solid Waste Management Plan

AGENCY: Environmental Protection Agency, Region 9.

ACTION: Final rule.

SUMMARY: As provided by the Resource Conservation and Recovery Act (RCRA), the Territory of Guam has received Federal financial assistance for development of a Territorial Solid Waste Management Plan. On July 13, 1982, the Territory of Guam submitted to the U.S. Environmental Protection Agency (EPA) its adopted Solid Waste Management Plan. Today, EPA is announcing its approval of the Guam Solid Waste Management Plan. Approval of the Guam plan indicates that the plan meets the requirements set forth in RCRA, which provides for the identification of responsibilities for solid waste management; the encouragement of resource conservation and recovery; and the development and application of State controls to provide for environmentally sound solid waste disposal practices.

The purpose of this notice is to inform the public that EPA is approving the Guam Solid Waste Management Plan. This approval should be of special interest because of two provisions of RCRA. First, RCRA requires that effective with the date of approval, plans prohibit the establishment of open dumps in the State. Second, only States with approved plans can establish compliance schedules, for purposes of RCRA, for entities engaged in open dumping. These compliance schedules lead to the upgrading of facilities classified as open dumps by September 13, 1984. Open dumping is prohibited by RCRA except where the practice is on a compliance schedule established under an EPA approved State plan.

EFFECTIVE DATE: October 29, 1982.

FOR FURTHER INFORMATION CONTACT: Karen Schwinn, Toxics and Waste Programs Branch, U.S. EPA, Region 9, 215 Fremont Street, San Francisco, CA 94105, (415) 974-8158.

SUPPLEMENTARY INFORMATION:

Background

On July 31, 1979, (44 *FR* 45066) EPA published Guidelines for the Development and Implementation of State Solid Waste Management Plans. These guidelines were required by Section 4002(b) of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA). The guidelines reflected the statutory requirements for State plans and recommended methods and procedures to meet those requirements. Under Section 4007 of RCRA, the Administrator approves State plans which meet the requirements of paragraphs (1), (2), (3), and (5) of Section 4003 of RCRA and which contain provisions for revisions. Briefly, these requirements are:

1. The plan shall identify the responsibilities of State, local and regional authorities in the implementation of the State plan; the distribution of Federal funds to the authorities responsible for development and implementation of the State plan; and the means for coordinating regional planning and implementation under the State plan;

2. The plan shall prohibit the establishment of new open dumps within the State and contain requirements that all solid waste shall be utilized for resource recovery or disposed of in sanitary landfills, as defined by Section 4004(a) of RCRA, or otherwise disposed of in an environmentally sound manner. The State prohibition must be effective as of the date on which EPA approves the plan;

3. The plan shall provide for the closing or upgrading of all existing open dumps within the State;

4. The plan shall provide that no local government within the State shall be prohibited under State or local law from entering into long-term contracts for the supply of solid waste to resource recovery facilities; and

5. The plan must contain specific provisions for revision.

The guidelines also addressed Section 4005 of RCRA which requires a mechanism in the State plan for establishment of compliance schedules for entities engaged in the prohibited act of open dumping. The plan must provide that, in attempting to obtain such compliance schedules, entities must demonstrate their inability to utilize other public or private alternatives to comply with the prohibition.

Response to Public Comments

On August 20, 1982, (47 FR 36451) a notice was published in the **Federal Register** inviting the public to submit written comments on the Guam Solid Waste Management Plan by September 20, 1982. No comments were received during this period.

Finding

Section 4007 of RCRA contains the statutory policy for approval of State plans. The authority to approve State plans under Section 4007 of RCRA has been delegated to the Regional Administrator. EPA has reviewed the Solid Waste Management Plan submitted by the Territory of Guam and has found that the Guam plan meets the requirements of RCRA for approval. Under authority of Section 4007 of RCRA, EPA hereby approves the Guam Solid Waste Mangement Plan. The plan prohibits the establishment of open dumps. The plan also provides for compliance schedules for entities engaged in open dumping where those entities can demonstrate that they are unable to utilize other public or private alternatives for solid waste management to comply with the RCRA prohibition of open dumping. As of this date, entities engaged in open dumping may, pursuant to the plan, approach the Territory for further information on compliance schedules and necessary demonstrations. The RCRA prohibition of open dumping does not extend to open dumping under such compliance schedules.

Compliance With Executive Order 12291

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

Certification Under the Regulatory Flexibility Act

I certify under 5 U.S.C. 605(b) that the approval of the Guam Solid Waste Management Plan will not have a significant economic impact on a substantial number of small entities. This approval will reduce burdens on small entities by establishing a mechanism to insulate them from citizen suits to enforce the open dumping prohibition. This rule, therefore, does not require a regulatory flexibility analysis.

List of Subjects in 40 CFR Part 256

Grant programs, Environmental protection, Waste treatment and disposal.

(90 Stat. 2817, 42 U.S.C. 6947)

Dated: October 15, 1982.

Sonia F. Crow,

Regional Administrator.

[FR Doc. 82-29864 Filed 10-28-82: 8:45 am]

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