of 1 percent ivermectin injection for treatment and control of grubs (*Hypoderma bovis*) in American bison. The supplemental NADA is approved as of December 19, 1997, and the regulations are amended in 21 CFR 522.1192 in paragraph (a)(2) and by adding new paragraph (d)(6) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

A tolerance for residues of ivermectin in the edible tissues of bison has not previously been established. At this time, a tolerance for residues of ivermectin and its metabolites in American bison is established in § 556.344 (21 CFR 556.344). Also, § 556.344 is revised to reflect a newer format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.1192 is amended in paragraph (a)(2) by revising the heading and by adding new paragraph (d)(6) to read as follows:

§ 522.1192 Ivermectin injection.

(a) * * *

(2) *Cattle, reindeer, swine, and American bison.* * * *

(d) * * *

(6) *American bison*—(i) *Amount.* 200 micrograms per kilogram (10 milligrams per 110 pounds) of body weight.

(ii) *Indications for use.* It is used in American bison for the treatment and control of grubs (*Hypoderma bovis*).

(iii) *Limitations.* For subcutaneous use. Do not slaughter within 56 days of last treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.344 is revised to read as follows:

§ 556.344 Ivermectin.

The marker residue used to monitor the total residues of ivermectin and its metabolites in American bison is 22,23-dihydroavermectin B_{1a}. The target tissue is liver. A tolerance is established for 22,23-dihydroavermectin B_{1a} in liver as follows:

(a) *Cattle*: 100 parts per billion.
(b) *Swine*: 20 parts per billion.
(c) *Sheep*: 30 parts per billion.
(d) *Reindeer*: 15 parts per billion.
(e) *American bison*. 15 parts per billion.

Dated: January 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–3896 Filed 2–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Tricaine Methanesulfonate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Western Chemical, Inc. The ANADA provides for the use of tricaine methanesulfonate in the water of fish and other cold-blooded aquatic animals for temporary immobilization.

EFFECTIVE DATE: February 17, 1998

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248, is the sponsor of ANADA 200–226, which provides for the use of tricaine methanesulfonate powder to be mixed in the water of fish and other cold-blooded animals to be used for anesthesia and tranquilization. Western Chemical's ANADA 200–226 is approved as a generic copy of Argent Chemical Laboratories' NADA 42–427 Finquel®. The ANADA is approved as of November 21, 1997, and the regulations are amended in 21 CFR 529.2503(b) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.2503 [Amended]

2. Section 529.2503 *Tricaine methanesulfonate* is amended in paragraph (b) by removing ''No.

051212'' and adding in its place ''Nos. 050378 and 051212''.

Dated: January 21, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–3900 Filed 2–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 88P-0439]

Medical Devices; Reclassification and Codification of Suction Lipoplasty System for Aesthetic Body Contouring

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued an order in the form of a letter to the American Society for Aesthetic Plastic Surgery (ASAPS) reclassifying the suction lipoplasty system for use in aesthetic body contouring from class III (premarket approval) to class II (special controls). The reclassification is based on information regarding the device contained in a reclassification petition submitted by ASAPS and other publicly available information. Accordingly, the order is being codified in the Code of Federal Regulations. This action is taken under the Medical Device Amendments of 1976 (the 1976 amendments) as amended by the Safe Medical Devices Act of 190 (the SMDA).

DATES: This regulation becomes effective March 19, 1998. The reclassification order was approved January 5, 1998

FOR FURTHER INFORMATION CONTACT: Stephen P. Rhodes, Center for Devices and Radiological Health (HFZ09410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 9409295) and the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 10109629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are: Class I (general controls), class II (special controls), and class III (premarket approval).

Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance. The SMDA broadened the definition of class II devices to mean those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary under section 513(a)(1)(B) of the act.

It is the agency's position that it is not necessary to obtain a new reclassification recommendation from a panel which had recommended reclassification into class II prior to the SMDA. If a panel recommended that a device be reclassified from class III into class II under the 1976 definition of class II, which included only performance standards as a class II control, clearly the Panel's recommendation for class II status would not change if controls, in addition to performance standards, could be added.

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures under section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 513(f)(2) of the act provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of the Department of Health and Human Services (the Secretary) to reclassify the device into class I or class II. FDA's regulations in 1A860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(2)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device classification panel. If a petition is referred to a panel, the panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) a summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which petition was filed.

II. Recommendation of the Panel

On December 28, 1988, FDA filed the reclassification petition submitted by ASAPS that requested reclassification of the suction lipoplasty system from class III into class II. FDA consulted with the General and Plastic Surgery Devices Advisory Panel (the Panel) of the