S66286, not including the stainless steel designated as 303Pb (UNS S30360).

(2) Precious metals: Gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium, titanium.

Dated: August 19, 2009.

Alberta E. Mills,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. E9–20589 Filed 8–25–09; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA–2009–N–0381]

Advisory Committee; Tobacco Products Scientific Advisory Committee; Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Establishment of the Tobacco Products Scientific Advisory Committee. These actions are needed to implement the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act. Elsewhere in this issue of the **Federal Register**, FDA is publishing two separate documents requesting nominations for voting and non-voting membership on this committee. This document also amends the agency's regulations to add the Tobacco Products Scientific Advisory Committee (the committee) to the agency's list of standing advisory committees.

DATES: This rule is effective August 26, 2009. The committee is being established and this charter will remain in effect until amended or terminated by the Commissioner of Food and Drugs (the Commissioner).

FOR FURTHER INFORMATION CONTACT: Erik P. Mettler, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4324, Silver Spring, MD 20993–0002, 301–796–4711, FAX: 301–847–3541, e-mail: *erik.mettler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The committee was established under 21 U.S.C. 387q, as added by section 917 of the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31). The committee is also governed by part 14 (21 CFR part 14), Public Law 92–463 (5 U.S.C. app.), and the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees. The committee advises the Commissioner or designee in discharging responsibilities as they relate to the regulation of tobacco products.

The committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

Specifically, the committee will submit reports and recommendations on tobacco-related topics, including the following:

- The impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics and other racial and ethnic minorities;
- The nature and impact of the use of dissolvable tobacco products on the public health, including such use on children;
- The effects of the alteration of nicotine yields from tobacco products and whether there is a threshold level below which nicotine yields do not product dependence on the tobacco product involved; and
- Any application submitted by a manufacturer for a modified risk tobacco product.

The committee may provide recommendations to the Secretary of Health and Human Services regarding any regulations to be issued under the Federal Food, Drug, and Cosmetic Act and may review any applications for new tobacco products or petitions for exemption under section 906(e) of the Family Smoking Prevention and Tobacco Control Act. The committee may consider and provide recommendations on any other matter as provided in the Family Smoking Prevention and Tobacco Control Act.

The committee shall consist of 12 members including the Chair. Members and the Chair are selected by the Commissioner or designee from among individuals knowledgeable in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The committee shall include nine technically qualified voting members, selected by the Commissioner or designee. The nine voting members shall be physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty. One member shall be an officer or employee of a State or local government or of the Federal Government. The final voting member shall be a representative of the general public. In addition to the voting members, the committee shall include three nonvoting members who are identified with industry interests. These members shall include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry. This final position can be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the committee.

The Commissioner or designee shall designate one of the voting members of the committee to serve as chairperson.

As added by section 917 of the Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. 387q(d)(3) provides that section 14 of the Federal Advisory Committee Act does not apply to this committee.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely amends the information in § 14.100 to reflect the establishment of the committee.

Therefore the agency is amending § 14.100(a) as set forth in the regulatory text of this document.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended to read as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155.

■ 2. In § 14.100, add paragraph (a)(5) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(a) * * *

(5) *Tobacco Products Scientific Advisory Committee.*

(i) Date Established: August 12, 2009.

(ii) Function: The committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner of Food and Drugs. Specifically, the committee will submit reports and recommendations on tobacco-related topics, including: The impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics and other racial and ethnic minorities; the nature and impact of the use of dissolvable tobacco products on the public health, including such use on children; the effects of the alteration of nicotine yields from tobacco products and whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and any application submitted by a manufacturer for a modified risk tobacco product. The committee may provide recommendations to the Secretary of Health and Human Services regarding any regulations to be issued under the Federal Food, Drug, and Cosmetic Act and may review any applications for new tobacco products or petitions for exemption under section 906(e) of the Family Smoking Prevention and Tobacco Control Act. The committee may consider and provide recommendations on any other matter as provided in the Family Smoking Prevention and Tobacco Control Act.

* * * * *

Dated: August 19, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–20485 Filed 8–26–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 516

[Docket No. FDA–2008–N–0176; Formerly Docket No. 2008N–0011]

RIN 0910–AG03

Defining ''Small Number of Animals'' for Minor Use Designation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The designation provision of the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) provides incentives to animal drug sponsors to encourage drug development and approval for minor species and for minor uses in major animal species. Congress provided a statutory definition of ''minor use'' that relied on the phrase ''small number of animals'' to characterize such use. At this time, the Food and Drug Administration (FDA) is amending the implementing regulations of the MUMS Act. In response to Congress' charge to the agency to further define minor use, this amendment establishes a specific ''small number of animals'' for each of the seven major animal species to be used in determining whether any particular intended use in a major species is a minor use.

DATES: This rule is effective November 9, 2009.

FOR FURTHER INFORMATION CONTACT: Meg Oeller, Center for Veterinary Medicine (HFV–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9005, e-mail: *Margaret.Oeller@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 18, 2008 (73 FR 14411), FDA issued a proposed rule (the March 2008 proposed rule) intended to define the term ''small number of animals'' for each of the seven major animal species to be used in determining whether any particular intended use in a major species is a minor use. As noted in that proposed rule, the MUMS Act (Public Law 108–282) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to provide incentives for the development of new animal drugs for use in minor animal species and for minor uses in major animal species. The MUMS Act defines ''minor use'' as ''the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually'' (section 201(pp) of the FD&C Act (21 U.S.C. 321(pp))). The major species are cattle, horses, swine, chickens, turkeys, dogs, and cats (section 201(nn) of the FD&C Act (21 U.S.C. 321(nn))).

Prior to enactment of the MUMS Act, FDA defined by regulation minor use to mean ''the use of: * * * (b) new animal drugs in any animal species for the control of a disease that (1) occurs infrequently or (2) occurs in limited geographical areas'' (formerly 21 CFR 514.1(d)(1)). The MUMS Act narrowed this definition by restricting it to uses ''in only a small number of animals annually'' (section 201(pp) of the FD&C Act).

The legislative history of the MUMS Act indicates that Congress intended that FDA further define by regulation minor use in a major species and that it do so ''by evaluating, in the context of the drug development process, whether the incidence of a disease or condition occurs so infrequently that the sponsor of a drug intended for such use has no reasonable expectation of its sales generating sufficient revenues to offset the cost of development'' (see S. Rept. 108–226 at 12–13). The legislative history also notes that the new statutory definition for minor use ''incorporates the existing definition in the Code of Federal Regulations (21 CFR 514.1(d)(1)) with a further limitation to small numbers to assure that such intended uses will not be extended to a wider use'' (see S. Rept. 108–226 at 12–13).

Therefore, while the MUMS Act establishes incentives for animal drug development for minor uses, it also limits the availability of those incentives in order to prevent them from stimulating ''wider use'' of new animal drugs marketed under MUMS Act provisions.

Consistent with these dual aims of stimulating animal drug development for minor uses in major species and at the same time preventing ''wider use'' of such new animal drugs, the agency is now defining the term ''small number of animals'' by establishing for each major species a number that would constitute the upper limit of a ''minor use'' under the MUMS Act. In keeping with the goal of creating a drug development incentive, this definition establishes the number of animals eligible to be treated annually based on the number of animals that represents a drug market value that (relative to drug development costs) would not be likely to be pursued