

boxes and baskets with painted or carved lids.

Wooden objects from this era are mainly preserved when painted with lacquer. These include architectural elements, utensils, coffins, musical instruments, and wood sculptures.

VII. Bamboo and Paper

Zhou through Tang: Types include texts on bamboo and wooden slips, and on paper. The slips may be found singly, or in groups numbering into the thousands. Some Buddhist sutras were printed with movable wooden type.

VIII. Glass

Zhou through Tang: Glass types include mostly tablewares, such as cups, plates, saucers.

IX. Painting and Calligraphy

A. Wall Painting

Note that this section includes wall art at least 250 years old as of January 14, 2009. The painted bricks of the Han through Tang tomb walls have already been mentioned. That tradition is partially concurrent with a fresco tradition that runs from the Han through Qing Dynasties. Temples including those in caves or grottos have wall paintings with Buddhist, Confucian, and Daoist themes.

B. Other Painting

Han through Tang: Paintings, dating to as early as the Southern and Northern, are on such media as banners, hand-scrolls, and fans. Subjects are drawn from Buddhism, Confucianism, and Daoism. Other subjects include landscapes and hunting scenes.

Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure or a delayed effective date (5 U.S.C. 553(a)(1)).

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) do not apply.

Executive Order 12866

Because this rule involves a foreign affairs function of the United States, it is not subject to Executive Order 12866.

Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1).

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise.

Amendment to CBP Regulations

For the reasons set forth above, part 12 of Title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

■ 2. In § 12.104g, the table of the list of agreements imposing import restrictions on described articles of cultural property of State parties is amended in the entry for the People's Republic of China in the column headed "Cultural Property" by adding the words "as of January 14, 2009" after the word "old"; and in the column headed "Decision No." by adding "extended by CBP Dec. 14-02" immediately after "CBP Dec. 09-03".

Thomas S. Winkowski,
Acting Commissioner, U.S. Customs and Border Protection.

Approved: January 8, 2014.

Timothy E. Skud,
Deputy Assistant Secretary of the Treasury.

[FR Doc. 2014-00388 Filed 1-10-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA-2013-N-1687]

Advisory Committee; Pharmacy Compounding Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to update information regarding the Pharmacy Compounding

Advisory Committee in FDA's Center for Drug Evaluation and Research in the Agency's list of standing advisory committees. This updated information regarding the Committee includes changes to its charter to reflect the recent enactment of the Drug Quality and Security Act.

DATES: This rule is effective January 13, 2014.

FOR FURTHER INFORMATION CONTACT:

Jayne E. Peterson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX 301-847-8533, email: PCAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA announced the original establishment of the Pharmacy Compounding Advisory Committee (the Committee) and amended the regulations at § 14.100 (21 CFR 14.100) to add the Committee to the Agency's standing list of advisory committees in the **Federal Register** of March 10, 1998 (63 FR 11596). The Committee was established under authorities that included the Federal Advisory Committee Act (Pub. L. 92-463), section 1004 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 394), and section 503A of the FD&C Act (21 U.S.C. 353a), as enacted as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115), which exempted drugs compounded by pharmacies from the FD&C Act's new drug approval, adequate directions for use, and good manufacturing practice requirements if specified conditions, including two restrictions on commercial speech, were met. Section 503A of the FD&C Act as added by FDAMA also required the Agency to convene and consult with an advisory committee on compounding before issuing specified regulations.

In 2002, FDA terminated the Committee in response to the Supreme Court's decision in *Thompson, et al. v. Western States Medical Center Pharmacy, et al.* (535 U.S. 357 (2002)). That decision affirmed a decision of the U.S. Court of Appeals for the Ninth Circuit that held the speech related provisions of section 503A of the FD&C Act, as added by FDAMA, were unconstitutional. The Supreme Court held that the speech related restrictions in section 503A of the FD&C Act violated the First Amendment. The Ninth Circuit had also concluded that the unconstitutional speech restriction could not be severed from the other provisions of section 503A of the FD&C Act. The Supreme Court did not reach

this issue. Therefore, the Ninth Circuit's opinion invalidating section 503A of the FD&C Act in its entirety remained intact. FDA stated its view at the time, which was that the underlying authority in section 503A of the FD&C Act to establish the Pharmacy Compounding Advisory Committee was invalidated and without a statutory basis for the Committee, the Agency terminated the Committee (67 FR 70227, November 21, 2002).

Subsequently, in 2008, the U.S. Court of Appeals for the Fifth Circuit decided *Medical Center Pharmacy v. Mukasey* (536 F.3d 383 (5th Cir. 2008)), in which that court disagreed with the Ninth Circuit's holding regarding the severability of section 503A of the FD&C Act as added by FDAMA. The Fifth Circuit found the unconstitutional provisions of section 503A of the FD&C Act to be severable and that the other provisions could remain in effect. Based on this decision, FDA reestablished the Pharmacy Compounding Advisory Committee in 2012.

On November 27, 2013, the President signed into law the Drug Quality and Security Act (Pub. L. 113–54). This law removed the unconstitutional provisions from section 503A and added a new section 503B to the FD&C Act (21 U.S.C. 353b) that also requires FDA to consult with a Pharmacy Compounding Advisory Committee before issuing certain regulations pertaining to outsourcing facilities. As a result, FDA has amended the charter of the Pharmacy Compounding Advisory Committee to reflect the relevant statutory changes.

Under the amended charter, the Committee provides advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the FD&C Act and, as required, any other product for which FDA has regulatory responsibility, and makes appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner).

The Committee will be composed of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. Membership also includes representatives from the National Association of Boards of Pharmacy and the United States Pharmacopoeia, and representatives of patient and public health advocacy organizations. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-

Federal members of this committee will serve as special Government employees. The core of voting members may include one qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one or more non-voting members who are identified with industry interests.

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 updates information regarding the function of the Committee already set out in the charter, and updates information regarding the dates related to the Committee establishment in the list of standing advisory committees in § 14.100. Therefore, the Agency is amending § 14.100.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice requesting nominations for voting members of the Committee, a notice for industry organizations to participate in the nominations for and selection of industry representatives for the Committee, and a notice for consumer organizations to participate in the nominations for and selection of the consumer representative for the Committee.

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 as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

- 1. The authority citation for 21 CFR part 14 is revised 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; Pub. L. 113–54.

- 2. Section 14.100 is amended by revising paragraph (c)(18) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(18) Pharmacy Compounding Advisory Committee.

(i) Date re-established: April 25, 2012.

(ii) Function: Provides advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and makes appropriate recommendations to the Commissioner of Food and Drugs.

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Dated: January 7, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–00322 Filed 1–10–14; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9652]

RIN 1545–BI57

Sales-Based Royalties and Vendor Allowances

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the capitalization and allocation of royalties that are incurred only upon the sale of property produced or property acquired for resale (sales-based royalties). This document also contains final regulations relating to adjusting inventory costs for a type of an allowance, discount, or price rebate earned on the sale of merchandise (sales-based vendor chargebacks). These regulations modify the simplified production method and the simplified resale method of allocating capitalized costs between ending inventory and cost of goods sold. These regulations affect taxpayers that incur capitalizable sales-based royalties or earn sales-based vendor chargebacks.

DATES:

Effective date: These regulations are effective on January 13, 2014.

Comment date: Comments will be accepted until April 14, 2014.

Applicability date: For dates of applicability, see §§ 1.263A–1(l),