Availability of Rulemaking Documents

You can get an electronic copy of rulemaking documents using the Internet by—

1. Searching the Federal eRulemaking Portal (http://www.regulations.gov);
2. Visiting the FAA’s Regulations and Policies Web page at http://www.faa.gov/regulations_policies; or

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the docket number or notice number of this rulemaking.

You may access all documents the FAA considered in developing this proposed rule, including economic analyses and technical reports, from the Internet through the Federal eRulemaking Portal referenced in paragraph (1).

List of Subjects in 14 CFR Part 187

Administrative practice and procedure, Air transportation.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend Chapter 1 of Title 14, Code of Federal Regulations, as follows:

PART 187—FEES

1. The authority citation for part 187 continues to read as follows:


2. In part 187, Appendix B is amended by revising paragraph (e)(2) to read as follows:

   Appendix B to Part 187—Fees for FAA Services for Certain Flights

   * * * * *

   (e) * * *

   (2) A User (operator of an Overflight) is assessed a fee for each 100 nautical miles (or portion thereof) flown in each segment and type of U.S.-controlled airspace. Separate calculations are made for transiting Enroute and Oceanic airspace. The total fee charged for an Overflight between any entry and exit point is equal to the sum of these two charges. This relationship is summarized as:

   \[ R_{ij} = X * \text{DE}_{e} + Y * \text{DO}_{o} \]

   Where:

   \[ R_{ij} = \text{the fee charged to aircraft flying between entry point i and exit point j} \]

   \[ \text{DE}_{e} = \text{total great circle distance traveled in each segment of U.S.-controlled Enroute airspace expressed in hundreds of nautical miles for aircraft flying between entry point i and exit point j for each segment of Enroute airspace} \]

   \[ \text{DO}_{o} = \text{total great circle distance traveled in each segment of U.S.-controlled Oceanic airspace expressed in hundreds of nautical miles for aircraft flying between entry point i and exit point j for each segment of Oceanic airspace} \]

   \[ X \text{ and } Y = \text{the values respectively set forth in the following schedule:} \]

<table>
<thead>
<tr>
<th>Time period</th>
<th>X (Enroute)</th>
<th>Y (Oceanic)</th>
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* * * * *

Issued in Washington, DC, on September 22, 2010.

Carl W. Burrus,
Director, Office of Financial Controls.

[FR Doc. 2010–24342 Filed 9–27–10; 8:45 am]
BILLING CODE 4910–13–P
swaps. The legislation was enacted to reduce risk, increase transparency, and promote market integrity within the financial system by, among other things: (1) Providing for the registration and comprehensive regulation of swap dealers and major swap participants; (2) imposing clearing and trade execution requirements on standardized derivative products; (3) creating robust recordkeeping and real-time reporting regimes; and (4) enhancing the Commission’s rulemaking and enforcement authorities with respect to, among others, all registered entities and intermediaries subject to the Commission’s oversight.

Section 723(c)(3) of the Dodd-Frank Act provides that swaps in an “agricultural commodity” (as defined by the Commission) are prohibited unless entered into pursuant to a rule, regulation or order of the Commission adopted pursuant to § 4(c) of the Commodity Exchange Act. This ANPRM reviews the current statutory and regulatory framework governing agricultural swaps, as well as the Dodd-Frank Act provisions applicable to agricultural swaps. The ANPRM then requests comment on the appropriate conditions, restrictions or protections to be included in any Commission rule, regulation or order governing the trading of agricultural swaps.

A. Current Statutory Framework for OTC Agricultural Swaps, Including Options Swaps

Since 2000, bilateral over-the-counter (“OTC”) swaps between certain sophisticated counterparties have been generally exempted from the Commission’s jurisdiction pursuant to current CEA § 2(g), which was added to the CEA by § 723 of the Dodd-Frank Act.

Prior to the Dodd-Frank Act, the Commission had defined a “swap” as follows: “A swap is a privately negotiated exchange of one asset or cash flow for another asset or cash flow. In a commodity swap [including an agricultural swap], at least one of the assets or cash flows is related to the price of one or more commodities.” 3 Prior to the Dodd-Frank Act, the Commission had defined a “swap” as follows: “A swap is a privately negotiated exchange of one asset or cash flow for another asset or cash flow. In a commodity swap [including an agricultural swap], at least one of the assets or cash flows is related to the price of one or more commodities.” [See 72 FR 66099, note 7 (November 27, 2007)]. See new CEA § 1a(47) for the statutory definition of a “swap,” as added to the CEA by § 723 of the Dodd-Frank Act.

Current § 2(g) provides:

Excluded swap transactions.

No provision of this chapter (other than section 5a [to the extent provided in section 5a(6)], 5b, 5d, or 12c(3)(B)) applies to or govern any agreement, contract, or transaction in a commodity other than an agricultural commodity if the agreement, contract, or transaction is—

1. Entered into only between persons that are eligible contract participants at the time they enter into the agreement, contract, or transaction;
2. Subject to individual negotiation by the parties; and
3. Not executed or traded on a trading facility. CEA § 2(g), 7 U.S.C. 2(g).

Modernization Act of 2000 (“CFMA”).

However, current § 2(g) specifically excludes an “agreement, contract, or transaction” in an “agricultural commodity” from the CFMA swaps exemption.

While the term “agricultural commodity” is not specifically defined in the Act, it is used in the Act in conjunction with the definition of the term “exempt commodity,” which is defined as neither an “agricultural commodity” nor an “excluded commodity.” There is limited legislative history regarding the CFMA to explain Congress’ intent in excluding “agricultural commodities” from the § 2(g) swaps exemption. However, the legislative history of H.R. 4541, the predecessor to the CFMA (H.R. 5660), which included the same basic structure of excluded and exempt commodities, indicates that Congress did not intend that the term “agricultural commodity” be limited to those commodities enumerated in the definition of the term “commodity” in current CEA § 1a(4).

The House Committee on Agriculture stated the following:

The Committee notes that the term “exempt commodity” means a commodity other than an “excluded commodity” or an “agricultural commodity.” For purposes of this definition, the Committee intends “agricultural commodity” to include all agricultural commodities, whether or not such agricultural commodities are specifically enumerated in the definition of “commodity” in section 1a(4) of the CEA.11 Notably, the definition of exempt commodity did not change from H.R. 4541 to H.R. 5660, the final version of the CFMA as enacted into law.

The effect of excluding agricultural commodities from current CEA § 2(g) was that swaps involving exempt and excluded commodities were allowed to transact largely outside of the Commission’s jurisdiction or oversight, while swaps involving agricultural commodities, including both the enumerated agricultural commodities and other non-enumerated agricultural commodities, remained subject to the Commission’s pre-CFMA swaps regulations as set forth in 17 CFR part 35.12

Options

The Dodd-Frank Act defines the term “swap” to include not only the various types of swaps listed in the definition, including commodity swaps and agricultural swaps, but also OTC options of any kind. Commodity options are subject to the Commission’s plenary authority under CEA § 4(c)(b). Based on § 4(c)(b)’s general prohibition of any option transactions contrary to any

12 Notably, current CEA § 2(g) is not the only statutory provision that excludes or exempts bilateral swaps between eligible contract participants from the Commission’s jurisdiction. Current CEA § 2(d)(1) excludes any such bilateral “contract, agreement, or transaction” in exempt commodities from Commission jurisdiction, while CEA § 2(b)(1) creates a similar exemption for a “contract, agreement or transaction” in exempt commodities. The overlap between these two provisions and the swap exemption in CEA § 2(g) serves to reinforce Congress’ clear intent to not exclude agricultural swaps from the Commission’s jurisdiction through the CFMA.
13 Exchange-traded futures and options on futures are specifically excluded from the Dodd-Frank swaps definition. See new CEA § 1a(47)(B), as added to the CEA by § 723 of the Dodd-Frank Act.
14 Section 4c(b) provides: Regularized option trading

No person shall offer to enter into, enter into or confirm the execution of, any transaction involving any commodity regulated under this Act which is of the character of, or is commonly known to the trade as, an “option,” “privilege,” “indemnity,” “bid,” “offer,” “put,” “call,” “advance guaranty,” or “decline guaranty,” contrary to any rule, regulation, or order of the Commission prohibiting any such transaction or allowing any such transaction under such terms and conditions as the Commission shall prescribe. Any such order, rule, or regulation may be made only after notice and opportunity for hearing, and the Commission may set different terms and conditions for different markets. CEA § 4c(b), 7 U.S.C. 6c(b).
Commission rule, regulation or order prohibiting options, or allowing them under such conditions as the Commission may prescribe, the only options currently authorized under the CEA are those specifically provided for in the Commission’s regulations.

B. Current Regulatory Framework

Swaps

As mentioned previously, Part 35 of the Commission’s regulations provides a broad-based exemption for certain swap agreements. Adopted by the Commission under its § 4(c) exemptive authority in 1993, Part 35 allows for swaps to transact OTC if certain conditions are met: (1) the swap agreements are entered into solely between eligible swap participants; (2) the swap agreements are not part of a fungible class of agreements that are standardized as to their material economic terms; (3) the creditworthiness of any party having an actual or potential obligation under the swap agreement must be a material consideration in entering into or determining the terms of the swap agreement, including pricing, cost, or credit enhancement terms; and (4) the swap agreement is not entered into and traded on a multilateral transaction execution facility.

After the CFMA amendments to the CEA, which excluded swaps on “exempt” and “excluded” commodities from virtually all of the Commission’s jurisdiction, Part 35 remained relevant only for agricultural swaps. With the exception of three outstanding § 4(c) exemptions related to cleared agricultural basis and calendar swaps,

Part 35 is the sole authority under which market participants may transact agricultural swaps that are not options.

Options

As noted above, the Commission maintains plenary authority over options pursuant to CEA § 4(c)(b). It has used that authority to, among other things, issue Part 32 of the Commission’s regulations, which includes a general ban on OTC options, but allows for OTC option transactions under certain conditions. Part 32 allows OTC options on agricultural commodities in two instances.

Rule 32.13 establishes rules for trading OTC options on the “enumerated” agricultural commodities ("agricultural trade options" or "ATOs") whereby ATOs may only be sold by an Agricultural Trade Option Merchant ("ATOM"), who must first register with the Commission as pursuant to CFTC rule 3.13. Since its 1998 adoption and one amendment following the 1999, the ATO registration scheme has attracted only one registrant, which registrant has since withdrawn its ATO registration. Accordingly, ATOs currently may only be transacted pursuant to an exemptive provision found at § 32.13(g)(1). The exemption at § 32.13(g)(1) allows ATOs to be sold when: (1) the option is offered to a commercial ("a producer, processor, or commercial user of, or a merchant handling" the underlying commodity); (2) the commercial enters the transaction solely for purposes related to its business as such; and (3) each party to the option contract has a net worth of not less than $10 million.

In either case (whether transacted pursuant to the ATOM registration scheme or accomplished via the exemption at § 32.13(g)), the phrase "agricultural trade option" refers specifically to an OTC option on an enumerated agricultural commodity.

In addition to the § 32.13(g) ATO exemption, Part 32 includes, at § 32.4, a basic trade option exemption applicable to options on commodities other than the enumerated agricultural commodities. The terms of the § 32.4 exemption are essentially the same as those of the § 32.13(g) exemption with one significant difference. Under § 32.4, the option must be offered to a producer, processor, or commercial user ("commercial") of the commodity, who enters into the commodity option transaction solely for purposes related to its business as such. However, § 32.4 does not include any net worth requirement.

Because the term “agricultural commodity” in the Act refers to more than just the enumerated commodities, the Commission recognizes that certain options authorized under § 32.4 (e.g. options on coffee, sugar, cocoa, and other agricultural products that do not appear in the enumerated commodity list) would also fall under the Dodd-Frank Act’s general prohibition of agricultural swaps (see discussion below of the Dodd-Frank rules for agricultural swaps and their implication for the existing agricultural swaps markets, including OTC options on agricultural commodities).

C. Dodd-Frank Provisions

Non-Agricultural Swaps

Under the CEA, as amended by the Dodd-Frank Act, only eligible contract participants ("ECPs") may enter into a swap, unless such swap is entered into on a designated contract market ("DCM"). In which case any person may enter into the swap.

New CEA § 2(h), as added by § 723(a)(3) of the Dodd-Frank Act, establishes a clearing requirement for

19 See 58 FR 5587 (Jan. 22, 1993). Note that because Part 35 was implemented pursuant to a § 4(c) exemption, agricultural swaps that rely on Part 35 for their legal authority will continue to be permitted under the Dodd-Frank language whereby existing agricultural swaps provisions adopted pursuant to § 4(c), including Part 35, are grandfathered. This is discussed more fully at section C, below.

20 See id. at 5590–5591; see also 17 C.F.R. § 35.2(a)–(d).

21 Part 35 at § 35.2(d), also provides that “any person may apply to the Commission for exemption from any of the provisions of the Act (except 2(a)(1)(B) [liability of principal for act of agent]) for other arrangements or facilities, on such terms and conditions as the Commission deems appropriate, including but not limited to, the applicability of other regulatory regimes.” See 17 CFR § 35.2(d). The Commission has granted three such exemptions, which have in each instance been styled as § 4(c) exemptive orders. See—

Order: (1) Pursuant to Section 4(c) of the Commodity Exchange Act (a) Permitting Eligible Swap Participants To Submit for Clearing and ICE Clear L., Inc., and Futures Commission Merchants To Clear Certain Over-The-Counter Agricultural Swaps and (b) Determining Certain Floor Brokers and Traders To Be Eligible Swap Participants; and (2) Pursuant to Section 4d of the Commodity Exchange Act, Permitting Certain Customer Positions in the Forgoing Swaps and Associated Property To Be Commingled With Other Property Held in Segregated Accounts, 73 FR 77015 (Dec. 18, 2008).

Order (1) Pursuant to Section 4(c) of the Commodity Exchange Act, Permitting the Chicago Mercantile Exchange To Clear Certain Over-the-Counter Agricultural Swaps and (2) Pursuant to Section 4d of the Commodity Exchange Act, Permitting Customer Positions in Such Cleared-Only Contracts and Associated Funds To Be Commingled With Other Positions and Funds Held in Customer Segregated Accounts, 74 FR 12316 (Mar. 24, 2009); and

Order (1) Pursuant to Section 4(c) of the Commodity Exchange Act, Permitting the Kansas City Board of Trade Clearing Corporation To Clear Over-the-Counter Wheat Calendar Swaps and (2) Pursuant to Section 4d of the Commodity Exchange Act, Permitting Customer Positions in Such Cleared-Only Swaps and Associated Funds To Be Commingled With Other Positions and Funds Held in Customer Segregated Accounts, 75 FR 34983 (June 21, 2010).

22 See Commission regulation 32.11, 17 CFR 32.11.

23 Note that Part 32 was not issued under the Commission’s § 4(c) exemptive authority. After the effective date of the Dodd-Frank Act, options on agricultural commodities will also fall under the Dodd-Frank Act’s provisions governing the trading of swaps (and, specifically, agricultural swaps) since options on commodities fall within the Act’s definition of a swap. Accordingly, it is important to identify what options on agricultural commodities are currently being traded pursuant to part 32.

24 63 FR 18821 (April 16, 1998); and 64 FR 68011 (December 6, 1998), respectively.

25 "Eligible contract participant" is defined in current CEA § 1a(12). Generally speaking, an eligible contract participant is considered to be a sophisticated investor.

26 A designated contract market is a board of trade designated as a contract market under CEA § 5.

27 See new CEA § 2(h) as added by § 723(a)(2) of the Dodd-Frank Act.
swaps. Under that subsection, the Commission would determine, based on factors listed in the statute, whether a swap, or a group, category, type, or class of swaps, should be required to be cleared. A swap entered into by a commercial end user is not subject to the mandatory clearing requirement; however an end user may opt to submit the swap for clearing. A swap that is required to be cleared must be executed on a DCM or a swap execution facility ("SEF"). If a DCM or SEF makes the swap available for trading. Swaps that are not required to be cleared may be executed bilaterally OTC.

Section 731 of the Dodd-Frank Act adds a new § 4s to the CEA that provides for the registration and regulation of swap dealers and major swap participants. The new requirements for swap dealers and major swap participants include, in part, capital and margin requirements, business conduct standards, and reporting, recordkeeping, and documentation requirements.

Section 731 of the Dodd-Frank Act amends current CEA § 4a regarding position limits. Under the Dodd-Frank provisions, the Commission must adopt position limits for futures, exchange-traded options, and swaps that are economically equivalent to futures and exchange-traded options within 180 days of the date of enactment of the Dodd-Frank Act for exempt commodities and within 270 days of the date of enactment of the Dodd-Frank Act for agricultural commodities.

Agricultural Swaps

Under § 723(c)(3) of the Dodd-Frank Act, swaps in an "agricultural commodity" (as defined by the Commission) are prohibited unless the swap is entered into pursuant to an exemption granted under CEA § 4(c). Generally speaking, § 4(c) provides that, in order to grant an exemption, the Commission must determine that: (1) The exemption would be consistent with the public interest and the purposes of the CEA; (2) any agreement, contract, or transaction affected by the exemption would not have a material adverse effect on the ability of the Commission or any contract market to discharge its regulatory or self-regulatory duties under the CEA.

Section 723(c)(3) includes a "grandfather" clause that provides that any rule, regulation, or order regarding agricultural swaps that was issued pursuant to § 4(c), and that was in effect on the date of enactment of the Dodd-Frank Act, would continue to be permitted. Such rules, regulations or orders would include Part 35 with respect to agricultural swaps and the agricultural basis and calendar swaps noted above, but would not include options entered into pursuant to Part 32.

D. Agricultural Commodities Definition

As noted above, § 723(c)(3) of the Dodd-Frank Act applies to any swap in an agricultural commodity "as defined by the Commodity Futures Trading Commission." The Commission plans to publish a proposed definition of the term "agricultural commodity" in the near future. That proposed definition will cover all such commodities that are, or could in the future be, traded pursuant to a swap or futures contract. However, for purposes of commenting on this ANPRM, commenters may assume that "agricultural commodity" includes the following commodities that are currently the subject of derivatives trading, whether listed for trading on a futures exchange or traded bilaterally OTC: (1) The enumerated commodities that are listed in current § 1a(4) of the CEA (e.g., corn, wheat, soybeans, livestock, cotton); (2) the international "soft commodities" (e.g., coffee, sugar, cocoa); (3) lumber, plywood and similar wood-derived commodities; (4) contracts based on underlying commodities listed in (1)–(3) (e.g., corn and wheat basis swaps and calendar swaps); and (5) other commodities derived from living organisms, including plant, animal or aquatic life, that are used for human food, animal feed or fiber, and that currently are the subject of derivatives trading. To the extent that any commenter is aware of any agricultural commodity that is not currently the subject of derivatives trading, but which they anticipate may be so traded in the future, and which might be affected by potential rules governing the trading of agricultural swaps, the Commission would welcome comments regarding such commodity.

Part II—Questions for Comment

Section 723(c)(3) of the Dodd-Frank Act and CEA § 4(c) authorize the Commission to impose such terms and conditions as it deems appropriate in order for a person to enter into or execute an agricultural swap. The Commission is requesting input on the following questions:

Current Agricultural Swaps Business

1. How big is the current agricultural swaps business—including both agricultural swaps trading under current part 35 and ATOs under §§ 32.4 and 32.13(g) of the Commission’s regulations?
2. What types of entities are participating in the current agricultural swaps business?
3. Are agricultural swaps/ATO participants significantly different than the types of entities participating in other physical commodity swaps/trade options?

Agricultural Swaps Clearing

4. What percentage of existing agricultural swaps trading is cleared vs. non-cleared?
5. What percentage of existing agricultural swaps would be eligible for the commercial end-user exemption from the mandatory clearing requirement?
6. What percentage of trading would be subject to the Dodd-Frank clearing requirement, if that requirement applied automatically to agricultural swaps (other than those eligible for the commercial end-user exemption)?
7. What would be the practical and economic effect of a rule requiring agricultural swaps transactions (other than those eligible for the commercial end-user exemption) generally to be cleared? The Commission is interested in the views of agricultural swaps market participants (both users and swap dealers) regarding a potential clearing requirement for agricultural swaps.
8. What would be the practical and economic effect of requiring agricultural swaps to be cleared under the Dodd-Frank clearing regime?

Trading

9. Have current agricultural swaps/ATO participants experienced any significant trading problems, including: (a) economic problems (i.e., contracts not providing an effective hedging mechanism, or otherwise not performing as expected); (b) fraud or other types of abuse; or (c) difficulty gaining access to the agricultural swaps market?

Agricultural Swaps Purchasers

10. Do agricultural swaps/ATO purchasers need more protections than...
participants in other physical commodity swaps/trade options?
11. If so, why, and what should those protections be?
12. Would additional protections for agricultural swaps purchasers unduly restrict their risk management opportunities?
13. Should the Commission consider rules to make it easier for agricultural producers to participate in agricultural swaps—for example, by allowing producers who do not qualify as ECPs to purchase agricultural swaps?

Designated Contract Markets

14. Should agricultural swaps transactions be permitted to trade on DCMs to the same extent as all other swaps are permitted on DCMs?
15. If yes, why?
16. If no, what other requirements, conditions or limitations should apply?

Swap Execution Facilities

17. Should agricultural swaps transactions be permitted on SEFs to the same extent as all other swaps are permitted to transact on SEFs?
18. If yes, why?
19. If no, what other requirements, conditions or limitations should apply?

Trading Outside of DCMs and SEFs

20. Should agricultural swaps be permitted to trade outside of a DCM or SEF to the same extent as all other swaps?
21. If yes, why?
22. If no, what other requirements, conditions or limitations should apply?
23. Should agricultural swaps be permitted to trade outside of a DCM or SEF to a different extent than other swaps due to the nature of the products and/or participants in the agricultural swaps market?
24. In general, should agricultural swaps be treated like all other physical commodity swaps under Dodd-Frank?
25. If yes, why?
26. If no, are there any additional requirements, conditions or limitations not already discussed in other answers that should apply?

27. If agricultural swaps are generally treated like swaps in other physical commodities, are there specific agricultural commodities that would require special or different protections?

Issued in Washington, DC, on September 21, 2010, by the Commission.

David A. Stavick, Secretary of the Commission.

[FR Doc. 2010–24198 Filed 9–27–10; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2010–N–0429]

Immunology and Microbiology Devices; Reclassification of the Herpes Simplex Virus Serological Assay Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the special controls for the herpes simplex virus (HSV) serological assay device type, which is classified as class II (special controls). These device types are devices that consist of antigens and antisera used in various serological tests to identify antibodies to herpes simplex virus in serum, and the devices that consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify herpes simplex virus directly from clinical specimens or tissue culture isolates derived from clinical specimens. Elsewhere in this issue of the Federal Register, FDA is announcing the availability of the revised draft guidance document entitled “Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays” that would serve as the special control for the device, if FDA amends the special controls. Because FDA is proposing to amend the special control for this device type, the agency is publishing the proposed rule that designates the revised guidance document as the special control for HSV serological devices.

DATES: Submit written or electronic comments on the proposed rule by November 29, 2010.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0429, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the “Paperwork Reduction Act of 1995” section of this document).

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• FAX: 301–827–6870.
• Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by email. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the ADDRESSES portion of this document under Electronic Submissions.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number(s), found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Haja Sittana El Mubarak, Center for Devices and Radiological Health, Bldg. 66, rm. 5519, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6193.

SUPPLEMENTARY INFORMATION:

1. Regulatory Authorities

The act (21 U.S.C. 301 et seq.), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), Safe Medical Devices Act (SMDA) (Public Law 101–629), Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115), and the Medical Device User Fee and Modernization Act (MDUFMA) (Public Law 107–250), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c) established three categories (classes) of devices, defined...