

educational settings, such as schools, summer camps, or child care facilities, this type of a distribution strategy would not necessarily convert a general use product into a children's product. However, if the product is packaged in such a manner that either expressly states or implies with graphics, themes, labeling, or instructions that the product is designed or intended primarily for children 12 years of age or younger, then it may be considered a children's product if the required consideration of all four statutory factors supports that determination. The requirements of the Labeling of Hazardous Art Materials Act are similar to the labeling requirements of the FHSA, of which it is a part. Therefore, third party testing to LHAMA is not required. An art material designed or intended primarily for children 12 years of age or younger would have to be tested by a third party laboratory to demonstrate compliance with CPSIA, but it would not require third party testing and certification to the LHAMA requirements. For the same reasons, no general conformity certificate is required for general use art materials.

(6) Books—The content of a book can determine its intended audience. Children's books have themes, vocabularies, illustrations, and covers that match the interests and cognitive capabilities of children 12 years of age or younger. The age guidelines provided by librarians, education professionals, and publishers may be dispositive for determining the intended audience. Some children's books have a wide appeal to the general public, and in those instances, further analysis may be necessary to assess who the primary intended audience is based on consideration of relevant additional factors, such as product design, packaging, marketing, and sales data.

(7) Science Equipment—Microscopes, telescopes, and other scientific equipment that would be used by an adult, as well as a child, are considered general use products. Equipment that is intended by the manufacturer for use primarily by adults, although there may be use by children through such programs, is a general use product. Toy versions of such items are considered children's products. If a distributor or retailer sells or rents a general use product in bulk through distribution channels that target children 12 years of age or younger in educational settings, such as schools or summer camps, this type of a distribution strategy would not necessarily convert a general use product into a children's product. However, if the product is packaged in such a manner that either expressly states or implies with graphics, themes,

labeling, or instructions that the product is designed or intended primarily for children 12 years of age or younger, then it may be considered a children's product if the required consideration of all four statutory factors supports that determination. Products mainly intended for use by the instructor would not be considered children's products. In general, scientific equipment that is specifically sized for children, such as protective gear, eyewear, gloves, or aprons and/or has childish themes or decorations and invites use by a child 12 years of age or younger or is marketed to appeal primarily to children is considered a children's product.

(8) Sporting Goods and Recreational Equipment—Sporting goods that are intended primarily for consumers older than 12 years of age are considered general use items. Sporting equipment, sized for adults, are general use items even though some children 12 years of age or younger will use them. Unless such items are specifically marketed to children 12 years of age or younger, or have extra features that make them more suitable for children 12 years of age or younger than for adults, they would be considered general use products. If children 12 years or younger would mainly use the product because it would be too small or inappropriate for older children to use, then it likely would be considered a children's product. Likewise, recreational equipment, such as roller blades, skateboards, bicycles, camping gear, and fitness equipment are considered general use products unless they are sized to fit children 12 years of age or younger and/or are decorated with childish features by the manufacturer.

(9) Musical Instruments—Musical instruments, including electronically-aided instruments suited for an adult musician, are general use products. Instruments intended primarily for children can be distinguished from adult instruments by their size and marketing themes. The Commission notes that if a distributor or retailer sells or rents in bulk, a general use musical instrument through distribution channels that target children 12 years of age or younger in educational settings, such as schools or summer camps, this type of a distribution strategy would not necessarily convert a general use product into a children's product. However, if the product is packaged in such a manner that either expressly states or implies with graphics, themes, labeling, or instructions that the product is designed or intended primarily for children 12 years of age or younger, then it may be considered a children's

product if the required consideration of all four statutory factors supports that determination.

Dated: October 6, 2010.

**Todd A. Stevenson,**  
Secretary, Consumer Product Safety  
Commission.

[FR Doc. 2010-25645 Filed 10-13-10; 8:45 am]

BILLING CODE 6355-01-P

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## COMMODITY FUTURES TRADING COMMISSION

### 17 CFR Part 44

#### RIN 3038-AD24

### Interim Final Rule for Reporting Pre-Enactment Swap Transactions

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Interim final rule; request for public comment.

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**SUMMARY:** The Commodity Futures Trading Commission ("Commission" or "CFTC") is publishing for comment an interim final rule to implement new statutory provisions introduced by Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act"). Section 729 of the Dodd-Frank Act requires the CFTC to adopt, within 90 days of enactment of the Dodd-Frank Act, an interim final rule for the reporting of swap transactions entered into before July 21, 2010 whose terms had not expired as of that date ("pre-enactment unexpired swaps"). Pursuant to this mandate, the CFTC is today adopting an interim final rule requiring specified counterparties to pre-enactment unexpired swap transactions to report certain information related to such transactions to a registered swap data repository ("SDR")<sup>1</sup> or to the Commission by the compliance date to be established in reporting rules required under Section 2(h)(5) of the CEA, or within 60 days after an SDR becomes registered under Section 21 of the CEA, whichever occurs first. An interpretive note to the rule advises that counterparties that may be required to report to an SDR or the CFTC will need to preserve information pertaining to the terms of such swaps.

**DATES:** This interim final rule is effective October 14, 2010. Comments

<sup>1</sup> The term "swap data repository" is defined in Section 1a(48) of the Commodity Exchange Act ("CEA" or the "Act") to mean "any person that collects and maintains information or records with respect to transactions or positions in, or the terms and conditions of, swaps entered into by third parties for the purpose of providing a centralized recordkeeping facility for swaps."

on all aspects of the interim final rule must be received on or before November 15, 2010.

**ADDRESSES:** Comments may be submitted by any of the following methods:

- *Agency Web Site:* Follow the instructions for submitting comments at <http://www.federalregister.gov/agencies/commodity-futures-trading-commission>.

- *E-mail:* [peswapreport@cftc.gov](mailto:peswapreport@cftc.gov).
- *Mail:* Address to David A. Stawick, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to <http://www.cftc.gov>. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the established procedures in CFTC Regulation 145.9.<sup>2</sup>

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from [www.cftc.gov](http://www.cftc.gov) that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

**FOR FURTHER INFORMATION CONTACT:** Susan Nathan, Senior Special Counsel, Division of Market Oversight, Commodity Futures Trading Commission, Washington, DC 20581, at (202) 418.5133.

**SUPPLEMENTARY INFORMATION:** The Commission is adopting Part 44 to its Regulations under the Commodity Exchange Act as an interim final rule and is soliciting comment on all aspects of the rule. The Commission will carefully consider all comments received and will address them, where applicable, in connection with the permanent reporting rules required to be adopted by the Dodd-Frank Act.

## I. Background

On July 21, 2010, President Obama signed into law the Dodd-Frank Wall

Street Reform and Consumer Protection Act (“Dodd-Frank Act”).<sup>3</sup> Title VII of the Dodd-Frank Act<sup>4</sup> amended the Commodity Exchange Act (“CEA”)<sup>5</sup> to establish a comprehensive new regulatory framework for swaps and security-based 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.

Among other things, the Dodd-Frank Act requires that swaps be reported to a registered SDR or to the Commission if there is no registered SDR that would accept the swap. Section 723 of the Dodd-Frank Act adds Section 2(h)(5) to the CEA to require that pre-enactment swaps be reported to a registered SDR or to the Commission no later than 180 days after the effective date of that subsection.<sup>6</sup> By its terms, the effectiveness of this rule is governed by the effective date of the Dodd-Frank Act—July 16, 2011. Section 729 of the Dodd-Frank Act establishes, in new Section 4r of the CEA, reporting requirements that will remain in effect until the effective date of the permanent reporting rules to be adopted by the Commission pursuant to Section 2(h)(5) of the CEA.

Section 4r(a)(1) of the CEA, as amended, provides generally that each swap that is not accepted for clearing by

any derivatives clearing organization (“DCO”) must be reported to a swap data repository (“SDR”) registered in accordance with new Section 21 of the CEA<sup>7</sup> or, where there is no SDR that would accept the swap, to the Commission within the time period prescribed by the Commission. Section 4r(a)(2) specifies that each swap entered into before the date of enactment of the Dodd-Frank Act, the terms of which had not expired by the date of enactment of that Act, must be reported to a registered SDR or to the Commission, and directs the Commission to promulgate, within 90 days of enactment of the Dodd-Frank Act, an interim final rule providing for the reporting of such swaps. Section 4r(a)(2)(A) directs that such swaps be reported by a date not later than (i) 30 days after issuance of the interim final rule; or (ii) such other period as the Commission determines to be appropriate.

Consistent with this mandate, the Commission is adopting, in new Part 44 of the Commission’s regulations, Rule 44.02 to (i) establish a reporting time frame for unexpired pre-enactment swaps that is no later than 60 days from the date the appropriate SDR is registered with the Commission or by the compliance date established in the swap reporting rules required by Section 2(h)(5) of the CEA, whichever comes first; and (ii) require that counterparties specified in Section 4r(a)(3) report information concerning pre-enactment unexpired swaps to the Commission on request during the interim period. Finally, the Commission is specifying in an interpretive note (“Note”) to Rule 44.02(a) the information the Commission believes reporting entities should retain in order to comply with the reporting obligations in the rule.

## II. The Interim Final Rule

### A. Reconciling the Relevant Statutory Provisions

Sections 723 and 729 of the Dodd-Frank Act establish requirements for the reporting of pre-enactment swaps to SDRs or to the Commission; each provides generally that swaps must be reported pursuant to such rules or regulations as the Commission prescribes. Section 729 provides that swaps entered into prior to the July 21, 2010 enactment date and outstanding on

<sup>3</sup> See Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010), hereinafter cited as “Dodd-Frank Act.” The text of the Dodd-Frank Act may be accessed at <http://www.cftc.gov/LawRegulation/OTCDERIVATIVES/index.htm>.

<sup>4</sup> Pursuant to Section 701 of the Dodd-Frank Act, Title VII may be cited as the “Wall Street Transparency and Accountability Act of 2010.”

<sup>5</sup> 7 U.S.C. 1 *et seq.*

<sup>6</sup> (5) Reporting Transition Rules.—Rules adopted by the Commission under this section shall provide for the reporting of data, as follows:

(A) Swaps entered into on or before the date of the enactment of this subsection shall be reported to a registered swap data repository or the Commission no later than 180 days after the effective date of this subsection.

(B) Swaps entered into on or after such date of enactment shall be reported to a registered swap data Repository or the Commission no later than the later or—

(i) 90 days after such effective date; or such other time after entering into the swap as the Commission may prescribe by rule or regulation.

<sup>7</sup> Section 21, added by Section 728 of the Dodd-Frank Act, requires that SDRs directly or indirectly making use of the mails or any means or instrumentality of interstate commerce to perform the functions of an SDR be registered with the Commission, and establishes statutory duties applicable to registered SDRs.

that date (hereafter “pre-enactment unexpired swaps”) must be reported to a registered SDR or the CFTC not later than 30 days after the CFTC issues an interim final rule<sup>8</sup> or such other period determined by the CFTC. Section 723 similarly provides that the Commission must promulgate a rule that pre-enactment swaps must be reported to a registered SDR not later than 180 days after the effective date of the subsection.<sup>9</sup> The inconsistencies between these two reporting provisions must be reconciled in order to eliminate uncertainty with respect to the actual reporting requirements for pre-enactment swaps.

### 1. Section 729

Section 4r(a)(1) of the CEA, added by section 729 of the Dodd-Frank Act, provides generally that each swap that is not accepted for clearing by any DCO must be reported to an SDR described in new Section 21 of the CEA or, in the case where there is no SDR that would accept the swap,<sup>10</sup> to the Commission within the time period prescribed by the Commission. Specifically, pre-enactment swaps must, pursuant to new CEA Section 4r(a)(2)(A), be reported to a registered SDR, or to the Commission if no SDR would accept the swap, by a date that is not later than 30 days after the issuance of the interim final rule prescribed in new Section 4r(a)(2)(B)<sup>11</sup> or such other period as the Commission determines to be appropriate. Section 4r(a)(3) delineates the reporting obligations of the parties in specific circumstances.<sup>12</sup>

<sup>8</sup> The interim final rule must be promulgated within 90 days of enactment of the Dodd-Frank Act. See Section 4r(a)(2)(B).

<sup>9</sup> Section 774 of the Dodd-Frank Act describes the effective date as follows: “unless otherwise provided,” the provisions of Title VII shall take effect “on the later of 360 days after the date of enactment” or to the extent that a provision of Title VII requires a rulemaking, “not less than 60 days after publication of the final rule or regulation implementing” such provision of Title VII.

<sup>10</sup> The Commission believes that this circumstance might occur where no SDR has yet been approved or where no SDR has been approved for a particular asset class. In addition, it is conceivable that an SDR’s system might not be equipped to accept a particular bespoke swap transaction.

<sup>11</sup> Section 4r(a)(2)(B) provides that “[t]he Commission shall promulgate an interim final rule within 90 days of the date of enactment of this section providing for the reporting of each swap entered into before the date of enactment as referenced in subparagraph (A).” See Section 729 of the Dodd-Frank Act.

<sup>12</sup> For swaps in which only one counterparty is a swap dealer or major swap participant, that swap dealer or major swap participant shall report the swap (Section 4r(3)(A)); where one counterparty is a swap dealer and the other is a major swap participant, the swap dealer shall report the swap (Section 4r(3)(B)). With respect to any other swap not described in subsections (A) and (B), the

### 2. Section 723

Section 723 of the Dodd-Frank Act adds to the CEA new Section 2(h)(5), which similarly requires that the Commission adopt a reporting transition rule for swaps entered into before the date of enactment of that subsection. Section 2(h)(5) provides that such swaps shall be reported to a registered SDR or to the Commission no later than 180 days after the effective date of that subsection—or approximately 540 days after the date of enactment.

### 3. Legislative Intent

In a July 15, 2010 floor statement, Senator Lincoln addressed the inconsistencies between Sections 2(h)(5) and 4r(a)(2)(A) and emphasized that the provisions of these two sections “should be interpreted as complementary to one another to assure consistency between them. This is particularly true with respect to issues such as the effective dates of these reporting requirements \* \* \*.”<sup>13</sup>

#### *B. Scope and Coverage of the Interim Final Rule*

As noted, new Section 2(h)(5) does not contain the same qualifying language found in Section 4r(a)(2)(A), which limits the swaps that must be reported to pre-enactment swaps whose terms have not expired as of the date of enactment. In the Commission’s view, failure to limit the term “pre-enactment swaps” to “pre-enactment unexpired swaps” would require reporting of every swap that has ever been entered into.<sup>14</sup> There are obvious practical and operational difficulties in an interpretation that imposes reporting requirements on expired swaps: counterparties may not have kept thorough, complete—or indeed any—records of such transactions. Moreover, the argument can be made that a swap whose terms have expired is no longer a swap as defined in the Dodd-Frank Act. For these reasons, the Commission believes that the trades described in Section 2(h)(5) should be viewed as consistent with those described in

counterparties to the swap shall select a counterparty to report the swap (Section 4r(a)(3)(C)).

<sup>13</sup> Lincoln, “Wall Street Transparency and Accountability,” *Congressional Record* (July 15, 2010) at S5923.

<sup>14</sup> Financial historians believe that the first swap transaction was executed between the World Bank and IBM Corporation in 1981. See Paul C. Harding, *Mastering the ISDA Master Agreements (1992 and 2002)* (FT Prentice Hall, 3d Ed. 2010) at 9. As noted in the text accompanying this footnote, the operational difficulties in requiring reporting of all swaps executed since 1981 could be substantial, and the cost in terms of technology and human capital resources would far outweigh any potential benefits for swaps that have expired.

Section 4r(a)(2); that is, limited to those pre-enactment trades whose terms had not expired at the time of enactment—*i.e.*, July 21, 2010.

### 1. Reporting Obligations

Rule 44.02(a) requires that the designated counterparty to a pre-enactment unexpired swap transaction<sup>15</sup> submit, with respect to such transaction, the following information to a registered SDR or to the Commission: (i) A copy of the transaction confirmation in electronic form, if available, or in written form if there is no electronic copy; and (ii) if available, the time the transaction was executed. In addition, Rule 44.02(b) provides that a counterparty to a pre-enactment unexpired swap transaction must report to the Commission on request any information relating to such transaction during the time that this interim final rule is in effect. The Commission expects that such information would vary depending upon the needs of the Commission and may include actual as well as summary trade data. Such summary data may include a description of a swap dealer’s counterparties or the total number of pre-enactment swap transactions entered into by the dealer and some measure of the frequency and duration of those contracts. The Commission believes that this requirement will facilitate its ability to understand and evaluate the current market for swaps and may inform its analysis of other required rulemakings under the Dodd-Frank Act.

### 2. Reporting Party

Section 4r(a)(3) of the CEA specifies the party obligated to report a swap transaction: either a swap dealer, a major swap participant, or a counterparty to the transactions. These provisions apply to reporting under the interim final rule. Specifically, Section 4r(a)(3) provides, with respect to a swap in which only one counterparty is a swap dealer or major swap participant, it is that entity’s responsibility to report the swap. With respect to a swap in which one counterparty is a swap dealer and the other counterparty is a major swap participant, the swap dealer must report the swap; with respect to any other swap, the counterparties shall select one of them to report the swap. Rule 44.02(b) incorporates these provisions.

<sup>15</sup> The reporting obligations of specified counterparties are delineated in Section 4r(a)(3) of the CEA, as amended.

### 3. Effective Date for Reporting Pre-Enactment Unexpired Swaps

New CEA Section 4r(a)(2)(C) establishes that the reporting provisions of section 4r are effective immediately upon enactment of the Dodd-Frank Act, despite the fact that at this time (i) there are no registered SDRs to immediately accept the swap data; (ii) the Commission is not prepared to accept swap data; and (iii) the Commission has not adopted rules governing either the registration of swap dealers or major swap participants or the reporting and maintenance of such data and is not required to do so until 360 days after enactment of the Dodd-Frank Act.<sup>16</sup> In these circumstances, Section 4r should be read to require that the reporting obligation became effective on enactment of the Dodd-Frank Act and that counterparties who are subject to this obligation should, as of the date of enactment, retain all data relating to pre-enactment unexpired swaps until such time as reporting can be effected—e.g., when swap dealers and major swap participants, as well as the appropriate SDRs, have been registered, or when permanent regulations are enacted pursuant to Section 2(h)(5) of the CEA, whichever occurs first.

### 4. Record Retention

The pre-enactment swap transactions that must be reported pursuant to Section 4r of the CEA, as amended, and the new interim final rule (Part 44 of the Commission's Regulations) occurred prior to enactment of the Dodd-Frank Act. Accordingly, implicit in the reporting requirements established by Section 4r and Rule 44 is the obligation of each counterparty to such transactions to retain information and documents relating to the terms of the transaction. Rule 44.02 includes a Note to paragraphs (a)(1) and (2) advising counterparties to a pre-enactment unexpired swap that may be required to report such transaction to retain in its existing format all information and documents, to the extent and in such form as they presently exist, relating to the terms of the transaction. This information includes, but is not limited to: (i) Any information necessary to identify and value the transaction; (ii) the date and time of execution of the

transaction; (iii) information relevant to the price of the transaction; (iv) whether the transaction was accepted for clearing by any clearing agency or derivatives clearing organization, and if so the identity of such agency or organization; (v) any modification(s) to the terms of the transaction; and (vi) the final confirmation of the transaction. The Commission believes that counterparties that may be required to report such transactions should retain such information in order to comply with the reporting requirements of Rule 44.02. The information identified above and in the Note is designed to encompass material information about pre-enactment unexpired swap transactions that may be the subject of a request by the Commission to report pursuant to the interim final rule, as well as rules subsequently adopted pursuant to new Section 2(h)(5) of the CEA, and that will assist the Commission in performing its oversight functions under the CEA.

The Note does not require any counterparty to a pre-enactment unexpired swap to create or retain new records with respect to transactions that occurred in the past. Permitting records to be retained in their existing format is designed to ensure that important information relating to the terms of pre-enactment unexpired swaps is preserved with minimal burden on the counterparties. Similarly, the Commission understands that information that the counterparty does not have prior to the effective date of the interim final rule cannot be reported.

## III. Related Matters

### A. Administrative Procedure Act

The Administrative Procedure Act<sup>17</sup> ("APA") generally requires an agency to publish notice of a proposed rulemaking in the **Federal Register**.<sup>18</sup> This requirement does not apply, however, when the agency "for good cause finds \* \* \* that notice and public procedure are impracticable, unnecessary, or contrary to the public interest."<sup>19</sup> Moreover, while the APA requires generally that an agency publish an adopted rule in the **Federal Register** 30 days before it becomes effective, this requirement does not apply if the agency finds good cause to make the rule effective sooner.<sup>20</sup> Section 729 of the Dodd-Frank Act amended the CEA to add new Section 4r, which in turn requires the Commission to adopt, within 90 days of enactment of the

Dodd-Frank Act, an interim final rule providing for the reporting of swaps entered into before the date of enactment of the Dodd-Frank Act the terms of which were not expired as of that date. The Commission is adopting Part 44 to its Regulations in response to this mandate. In these circumstances, the Commission, for good cause, finds that notice and solicitation is impracticable, unnecessary or contrary to the public interest. This finding also satisfies the requirements of 5 U.S.C. 808(2), permitting the rule to become effective notwithstanding the requirement of 5 U.S.C. 801 (if a federal agency finds that notice and public comment are "impractical, unnecessary or contrary to the public interest," a rule "shall take effect at such time as the federal agency promulgating the rule determines.").

### B. Paperwork Reduction Act

#### 1. Reporting Requirements

The Commission has determined that these proposed orders will not impose on swap counterparties any new reporting requirements that would be collections of information requiring the approval of the Office of Management and Budget under the Paperwork Reduction Act.<sup>21</sup> The reporting requirements associated with Section 723 of the Dodd-Frank Act will be adopted by the Commission, at which time the Commission will issue a notice and request comments on the reporting requirements and seek OMB approval as provided by 5 CFR 1320.8 and 1320.11.

#### 2. Recordkeeping Requirements

Proposed Commission Regulation 44.02 imposes a recordkeeping requirement on swap counterparties that is considered to be a collection of information within the meaning of the Paperwork Reduction Act ("PRA").<sup>22</sup> The Commission therefore is required to submit to the Office of Management and Budget (OMB) an information collection request for review and approval in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.8 and d1320.11. The Commission will, by separate action, publish in the **Federal Register** a notice and request for comments on the paperwork burden associated with these recordkeeping requirements in accordance with 5 CFR 1320.8. If approved, this new collection of information will be mandatory.

### C. Cost-Benefit Analysis

Section 15 of the CEA requires the Commission to consider the costs and

<sup>16</sup> Section 2(h)(5) does not specify an effective date. In these circumstances, the "default" effective date would be 360 days after enactment of the Dodd-Frank Act or 60 days after publication of a final rule or regulation. Adoption of the effective date prescribed in Section 2(h)(5) permits the implementation of Section 4r and achieves Senator Lincoln's goal of assuring consistency between the two legislative provisions embodied in Sections 4r and 2(h)(5).

<sup>17</sup> 5 U.S.C. 553.

<sup>18</sup> 5 U.S.C. 553(b).

<sup>19</sup> *Id.*

<sup>20</sup> 5 U.S.C. 553(d).

<sup>21</sup> 44 U.S.C. 3501 *et seq.*

<sup>22</sup> 44 U.S.C. 3501 *et seq.*

benefits of its action before issuing a new regulation or order under the Act. By its terms, Section 15(a) does not require the Commission to quantify the costs and benefits of its action or to determine whether the benefits of the action outweigh its costs. Rather, Section 15(a) requires the Commission simply to “consider the costs and benefits” of the subject rule or order. Section 15(a) further specifies that the costs and benefits of Commission regulations shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of the market for listed derivatives; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission may, in its discretion, give greater weight to any one of the five enumerated areas of concern and may, in its discretion, determine that notwithstanding its costs, a particular regulation is necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the CEA.

Title VII of the Dodd-Frank Act requires the Commission to undertake a number of rulemakings to implement the regulatory framework for swaps set forth in that Act, including the reporting of swap transactions. This interim final rule implements the Dodd-Frank Act by establishing reporting requirements for pre-enactment unexpired swaps as required by Section 729 of that Act and serving as notice to reporting entities of a present obligation to retain data related to such swaps for reporting at a future date. The rule will enable the Commission to obtain data on pre-enactment swaps and will also provide for the preservation of data on such swaps until the Commission issues permanent recordkeeping and reporting rules for all swaps. By making available transaction data on pre-enactment swaps, this action will enable the Commission to gain a better understanding of the swap market—including the size and scope of that market; this understanding will ultimately lead to a more robust and transparent environment for the market for swaps. Further, the Commission expects this rule to make available information that could inform the Commission’s decision-making with respect to the rules it is required to implement under the Dodd-Frank Act.

The Note to Rule 44.02(a)(1) and (2) addresses the retention of records relating to swaps entered into before July 21, 2010, the terms of which had

not expired as of that date. Although there are recordkeeping costs associated with retention of existing swap transaction information, the Commission does not believe those costs will be significant. The rule does not require market participants to modify the data they have for retention purposes, and the information that is required to be reported should be information that is already kept by swap counterparties in their normal course of business, and it may be reported in the format in which it is kept. Moreover, counterparties must report the time of execution only to the extent such information is available.

The permanent reporting rules that the Commission is required to adopt under new CEA Section 2(h)(5) also will apply to pre-enactment swaps. Accordingly, in adopting this interim final rule, the Commission has sought to limit the burden on market participants by not imposing substantial or potentially conflicting reporting requirements.

#### *D. The Regulatory Flexibility Act*

The Regulatory Flexibility Act (“RFA”), 5 U.S.C. 601 *et seq.*, requires Federal agencies, in promulgating rules, to consider the impact of those rules on small entities. The term “rule” under the RFA is defined as “any rule for which the agency publishes a general notice of proposed rulemaking pursuant to Section 553(B) of this title, or any other law \* \* \*.”<sup>23</sup> However, a general notice of proposed rulemaking under Section 553(b) does not apply “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules [issued] that notice and public procedure thereon are impracticable, unnecessary or contrary to the public interest.”<sup>24</sup> Congress in Section 4r(a)(2)(B) of the CEA directs the Commission to promulgate an interim final rule within 90 days of enactment of the Dodd-Frank Act to require the reporting of unexpired pre-enactment swaps. The Commission believes that the RFA does not apply to this interim final rule because “good cause” under 5 U.S.C. 553(b) has been established by specific order of Congress in the Dodd-Frank Act.

#### **List of Subjects in 17 CFR Part 44**

Swap markets, Counterparties, Reporting and recordkeeping requirements.

■ In consideration of the foregoing, and pursuant to the authority in the

<sup>23</sup> 5 U.S.C. 601(2).

<sup>24</sup> 5 U.S.C. 553(b).

Commodity Exchange Act, as amended, and in particular Section 4r (a)(2) of the Act, the Commission hereby proposes to amend Chapter I of Title 17 of the Code of Federal Regulation by adding a new Part 44 as follows:

#### **PART 44—INTERIM FINAL RULE FOR PRE-ENACTMENT SWAP TRANSACTIONS**

Sec.

44.00 Definition of terms used in Part 44 of this chapter.

44.01 Effective date.

44.02 Reporting pre-enactment swaps to a swap data repository or the Commission.

**Authority:** 7 U.S.C. 2(h)(5), 4r, and 12a(5), as amended by Title VII of the Wall Street Reform and Consumer Protection Act (Dodd-Frank Act of 2010), Pub. L. 111–203, 124 Stat. 1376 (2010).

#### **§ 44.00 Definition of terms used in Part 44 of this chapter.**

(a) *Major swap participant* shall have the meaning provided in Section 1a(33) of the Commodity Exchange Act, as amended, and any rules or regulations thereunder.

(b) *Pre-enactment unexpired swap* means any swap entered into prior to the enactment of the Dodd-Frank Act of 2010 (July 21, 2010) the terms of which had not expired as of the date of enactment of that Act;

(c) *Reporting entity*, when used in this Part, means any counterparty referenced or identified in Section 4r(a)(3)(A)–(C) of the Commodity Exchange Act, as amended;

(d) *Swap Data Repository* shall have the meaning provided in Section 1a(48) of the Commodity Exchange Act, as amended, and any rules or regulations thereunder;

(e) *Swap Dealer* shall have the meaning provided in Section 1(a)(49) of the Commodity Exchange Act, as amended, and any rules or regulations thereunder;

#### **§ 44.01 Effective date.**

The provisions of this Part are effective immediately on publication in the Federal Register.

#### **§ 44.02 Reporting pre-enactment swaps to a swap data repository or the Commission.**

(a) A counterparty to a pre-enactment unexpired swap transaction shall:

(1) Report to a registered swap data repository or the Commission by the compliance date established in the reporting rules required under Section 2(h)(5) of the Commodity Exchange Act, or within 60 days after a swap data repository becomes registered with the Commission and commences operations to receive and maintain data related to such swap, whichever occurs first, the

following information with respect to the swap transaction:

(i) A copy of the transaction confirmation, in electronic form if available, or in written form if there is no electronic copy; and

(ii) The time, if available, that the transaction was executed; and

(2) Report to the Commission on request, in a form and manner prescribed by the Commission, any information relating to the swap transaction.

Note to Paragraphs (a)(1) and (a)(2). In order to comply with the reporting requirements contained in paragraph (a)(1) and (a)(2) of this section, each counterparty to a pre-enactment unexpired swap transaction that may be required to report such transaction should retain, in its existing format, all information and documents, to the extent and in such form as they presently exist, relating to the terms of a swap transaction, including but not limited to any information necessary to identify and value the transaction; the date and time of execution of the transaction; information relevant to the price of the transaction; whether the transaction was accepted for clearing and, if so, the identity of such clearing organization; any modification(s) to the terms of the transaction; and the final confirmation of the transaction.

(b) *Reporting party.* The counterparties to a swap transaction shall report the information required under paragraph (a) of this section as follows:

(1) Where only one counterparty to a swap transaction is a swap dealer or a major swap participant, the swap dealer or major swap participant shall report the transaction;

(2) Where one counterparty to a swap transaction is a swap dealer and the other counterparty is a major swap participant, the swap dealer shall report the transaction; and

(3) Where neither counterparty to a swap transaction is a swap dealer or a major swap participant, the counterparties to the transaction shall select the counterparty who will report the transaction.

By the Commission.

Dated: October 1, 2010.

**David A. Stawick,**

*Secretary.*

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**BILLING CODE 6351-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 529

[Docket No. FDA-2010-N-0002]

#### Certain Other Dosage Form New Animal Drugs; Progesterone Intravaginal Inserts

**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 a supplemental new animal drug application (NADA) filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The supplemental NADA provides for use of progesterone intravaginal inserts and dinoprost tromethamine by injection for synchronization of estrus in lactating dairy cows.

**DATES:** This rule is effective October 14, 2010.

**FOR FURTHER INFORMATION CONTACT:** Suzanne J. Sechen, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8105, *e-mail:* [suzanne.sechen@fda.hhs.gov](mailto:suzanne.sechen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017 filed a supplement to NADA 141-200 that provides for use of EAZI-BREED CIDR Progesterone Intravaginal Inserts and dinoprost tromethamine by injection for synchronization of estrus in lactating dairy cows. The NADA is approved as of July 22, 2010, and the regulations are amended in 21 CFR 529.1940 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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 Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33 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.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 529

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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.

■ 2. In § 529.1940, revise paragraphs (d)(2) and (e)(1) and remove the last sentence in paragraph (e)(2)(iii) to read as follows:

#### § 529.1940 Progesterone intravaginal inserts.

\* \* \* \* \*

(d) \* \* \*

(2) *Cows.* This product is approved with the concurrent use of dinoprost solution when used for indications listed in paragraphs (e)(1)(ii)(A) and (e)(1)(ii)(B) of this section. *See* § 522.690(c) of this chapter.

(e) \* \* \*

(1) *Cows*—(i) *Amount.* Administer one intravaginal insert per animal for 7 days. When used for indications listed in paragraph (e)(1)(ii)(A) of this section, administer 25 milligrams (mg) dinoprost (5 milliliters (mL) of 5 mg/mL solution as in § 522.690(a) of this chapter) as a single intramuscular injection 1 day prior to insert removal (Day 6). When used for indications listed in paragraph (e)(1)(ii)(B) of this section, administer 25 mg dinoprost as a single intramuscular injection on the day of insert removal (Day 7).

(ii) *Indications for use*—(A) For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers; for advancement of first postpartum estrus in suckled beef cows; and for advancement of first pubertal estrus in replacement beef heifers.

(B) For synchronization of estrus in lactating dairy cows.

(C) For synchronization of the return to estrus in lactating dairy cows