amended by the National Energy Conservation Policy Act, (Pub. L. 95–619) (1978), the National Appliance Energy Conservation Act, (Pub. L. 100–12) (1987), and the National Appliance Energy Conservation Amendments of 1988, (Pub. L. 100–357) (1988). 42 U.S.C. 6294; sec. 553 of the Administrative Procedure Act, 5 U.S.C. 553.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 91–21104 Filed 9–3–91; 8:45 am]

BILLING CODE 6750–01–M

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 5, 15 and 33

Domestic Exchange-Traded Commodity Options; Requirements for Option Contract Market Designation

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rules.

SUMMARY: The Commodity Futures Trading Commission ("CFTC" or "Commission") has determined to adopt as final the rules it proposed to remove or to amend relating to several of the requirements for designation of options on futures contracts (56 FR 14896 (April 12, 1991)). The commission proposed either to remove or to amend several of these requirements for designation based upon its recent review of all of its designation procedures. These requirements for designation of options on futures contracts have gone largely unchanged from the time option trading was made permanent, and in some instances, from the inception of the pilot option program.

Accordingly, Rule 33.4(a)(5)(iii), which requires a specified volume of trading in the underlying futures contract prior to designation; Rule 5.4, which establishes a delisting criterion for the trading of options on low-volume futures contracts; Rule 33.4(b)(1)(iv), which requires that exchanges adopt rules establishing a period of time before the expiration of an option during which no new option strike prices can be added; and Rule 33.4(g), which requires exchanges to provide a comprehensive list of occupational categories of commercial users of the commodity underlying the option are being removed. In addition, the Commission is revising Rule 33.4(d)(1), which requires exchanges to justify expiration dates of less than 10 days before first notice day or last trading day of the future, whichever comes first, and redesignating it as Rule 33.4(b)(2). The Commission also is amending Rule 15.00(b)(2), to raise to 50 contracts the minimum reportable level requiring no exchange justification.

EFFECTIVE DATE: October 4, 1991.

FOR FURTHER INFORMATION CONTACT: Blake Imel, Deputy Director, or Paul M. Architzel, Chief Counsel, Division of Economic Analysis, Commodity Futures Trading Commission, 2033 K. St. NW., Washington, DC 20581, (202) 254–3201 or 254–6990, respectively.

SUPPLEMENTARY INFORMATION:

I. Background

A. Paperwork Reduction Act

The Paperwork Reduction Act of 1980 (Act), 44 U.S.C. 3501 *et seq.*, imposes certain requirements on Federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the Paperwork Reduction Act. In compliance with the Act the Commission has submitted these amended rules and their associated information collection requirements to the Office of Management and Budget.

While these amended rules have no increased information collection burden associated with them, they are a part of a group of rules which has a public reporting burden which is estimated to average 50.34 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this estimate of no increased burden to Joe F. Mink, CFTC Clearance Officer, 2033 K Street, NW., 20581, and to the Office of Management and Budget, Paperwork Reduction Project (3038), N.E.O.B., Washington, DC 20503.

B. History of Option Trading in the United States

In enacting the Commodity Exchange Act in 1936, Congress, concerned with the history of excessive price movements and severe disruptions in the futures markets attributed to speculative trading in options, prohibited option trading in all of those commodities then regulated under the Act.[1] Massive fraud in the offer and sale of options in commodities not so enumerated in the Act occurred in the late 1960s and early 1970s. Consequently, in creating the new Commodity Futures Trading Commission, Congress granted it broad power to regulate transactions in options in the previously unregulated commodities.[2] Following a period when options were banned because of abuses,[3] the Congress, in 1982, authorized the Commission to implement a pilot program for the trading of options on futures contracts on designated contract markets. See section 206(2) of the Futures Trading Act of 1982, 96 Stat. 2294, 2301. It was against this background that the Commission promulgated its rules governing a three-year pilot program for the trading of options on domestic exchanges. Many of the rules that were promulgated in connection with options trading were in response to this prior history of abuses. Others were promulgated in light of the absence of any recent trading experience with exchange-traded option products, or to assess the success of the pilot program itself.

C. Designation Requirements for Options

Among the requirements for designation of option contracts was a limitation on the number of option contracts permitted on each exchange. 17 CFR 33.4 (1982). In addition, as a condition for designation of an option, the underlying futures contract was required to meet a quantitative test of liquidity. 17 CFR 33.4(a)(5)(iii)(1982). Moreover, option contract markets were required to provide rules establishing a period before the expiration of an option during which no new strike prices may be introduced, 17 CFR 33.4(b)(1)(iv); to justify an expiration date on the option if less than 10 business days before the earlier of the last trading day or the first notice day of the underlying futures contract, 17 CFR 33.4(d)(1); and to provide a list of occupational or business categories of commercial users of the commodity underlying the relevant futures contract, 17 CFR 33.4(g) (1982).[4]

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[1] Act of June 15, 1936, chapter 545, section 5, 49 Stat. 1484.

[2] Commodity Futures Trading Commission Act of 1974, Public Law No. 93–463, section 402(c), 886 Stat. 1412–13 (codified at 7 U.S.C. 6c(b)).

[3] See, 43 FR 16153, (April 17, 1978). This suspension was codified by the Congress when it enacted the Futures Trading Act of 1978, Public Law No. 95–406, 3, 92 Stat. 867.

[4] Many of the rules were promulgated in light of the lack of previous trading history in options. Among them were the liquidity requirement of Rule 33.4(a)(5)(iii) and the requirement that exchanges justify the expiration of an options contract less than 10 days before first notice date, or the last trading day of the underlying future, 17 CFR 33.4(d)(1).

Similarly, Commission Rule 33.4(g), which requires exchanges to provide, as part of the designation application, a comprehensive list of occupational or business categories of persons which they would consider commercial users of the physical commodity underlying the futures contract

Continued

Subsequently, as a consequence of the ending of the pilot status of the program, some of the designation criteria were modified, and others added. For example, in connection with removal of the numerical limitations on the number of option contracts which could be traded on any one exchange, the Commission determined to reconsider the liquidity test, raising the threshold volume level of the underlying futures contract for designation of an option on such a futures contract from 1,000 contracts per week to the current level of 3,000 contracts per week.[5] Coupled with the increase in the threshold limitation, the Commission adopted an alternative test which permitted the introduction of an options on a futures contract with less than a full year's trading history of the underlying futures.

In addition, the Commission promulgated a delisting criterion for options, Rule 5.4, which provided that if volume in the underlying futures contract fell below 1,000 contracts per week for the preceding six month period, no new option expirations could be added. Listing of expirations could be resumed once volume in the underlying futures contracts rose to the level of 2,000 contracts per week for a period of three months.[6]

II. The Proposed Rulemaking

A. The Proposed Rules

The Commission proposed to delete the volume requirement for the designation of, and the delisting requirement for, options on futures contracts based upon its experience in previously granting exemptions from these requirements in recent years. As the Commission noted in proposing to delete the volume requirement for designation, it:

> based its determinations on whether to grant such exemptions * * * on several factors. These included whether the option's underlying cash market exhibits a high level of liquidity, whether the terms of the underlying futures contract ensure the opportunity for arbitrage and close alignment between the cash and futures markets and whether an accurate and widely disseminated price series exists which is representative of values of the commodity underlying the future.
>
> [T]he experience of the Commission has been that no problems have been observed directly related to the volume of trading or lack thereof in the underlying futures at the time of designation, regardless of the particular characteristics of the cash markets or degree of liquidity of the futures markets for any of the option contracts for which exemptions have been approved.
>
> [T]rading history indicates that the prospective concerns of the Commission regarding the potential for disruption of an illiquid underlying futures market by the designation of an option contract on that futures have not materialized.

56 FR 14898.

Similarly, the Commission has observed no adverse affects from granting exemptions from the delisting requirement under Rule 5.4. As the Commission noted in proposing to delete this requirement:

> In light of the Commission's proposed deletion of the initial volume requirement, the delisting requirement must also be reconsidered. Because the initial volume requirement would no longer be in effect, if Rule 5.4 were not modified, virtually every designation would require the Commission to consider whether to grant an exemption from the delisting requirement. As detailed above, the Commission's concern at the outset of option trading, that such trading might have an adverse effect on illiquid futures markets or on the customers in such markets, has not been borne out. Moreover, the actual exemptions which have been granted have not resulted in any adverse effect on an options market, its underlying futures market, or to customers in either of the markets.

56 FR 14899.

Based upon its experience in designating new option contracts, the Commission proposed to amend Rule 33.4(d)(1) routinely to permit options on futures contracts which are settled through physical delivery to expire at any time prior to the day before first notice day or the last trading day, whichever comes first. Options on futures contracts which are cash-settled were proposed to be permitted to expire simultaneously with the underlying futures. In particular, the Commission based its proposal on its experience that in light of the book entry of expired options into positions in the underlying futures contracts, and in general, the existence of sufficient liquidity in the futures through the last trading day, expiration of the option could be moved closer to the last trading day than the currently recommended ten days without adverse impact. In this regard, the Commission noted that exchanges have demonstrated routinely that the related futures contract has sufficient liquidity, and, in the case of cash-settled futures, the Commission has approved simultaneous expiration of the option and its underlying futures.

However, in proposing this modification, the Commission noted that:

> those contract markets adopting an option expiration date less than ten days from the last trading day would be required, as part of an effective market surveillance program, to have daily large trader reports for the expiring option during the applicable period.

56 FR 14899.

The Commission also proposed to remove the requirement that exchanges provide for a period in which no new strike prices may be added (Commission Rule 33.4(b)(1)(iv)).[7] Its proposal was based upon the lack of particular problems or complaints arising from the listing of new strike prices during the period through the last trading day.[8] Moreover, the enhanced economic utility of the option for hedging, particularly in times of high volatility, which may result from permitting the listing of additional strike prices near expiration supported the removal of this requirement.

In addition, the Commission, based upon its experience and accumulated expertise, proposed to remove the requirement of Commission rule 33.4(g) that exchanges provide a comprehensive list of occupational or business categories of commercial users of the commodity underlying the option. As the Commission made clear in proposing to delete this requirement, however, it will continue to make appropriate modifications to these categories as appropriate and that it will continue to use these codes in future special calls.

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of which the option is traded, was promulgated to assist the Commission in determining the appropriate categories of commercial traders for these newly traded instruments.

[5] In so doing, the Commission reasoned that: an initial volume of 1,000 contracts per week generally may not be adequate to ensure that a trader would be able to exercise an option into a sufficiently liquid market so that the resulting position could be offset without suffering a substantial loss of the option's true economic value.

51 FR at 17467.

[6] The Commission determined that a delisting criterion was necessary based upon an expectation that with permanent status, the volume of trading in various option markets might fluctuate greatly over the years. The Commission noted that such a delisting criterion would establish: the minimum acceptable level below which the individual trader in the underlying futures market may be adversely affected by the existence of a derivative market.

51 FR 17469.

[7] Rule 33.4(b)(1)(iv) requires exchanges to adopt rules which prescribe the period of time before the expiration of an option during which no new strike prices may be introduced. Generally, exchanges provided that no new strike prices could be added during the month in which the options expire. This usually resulted in no new strike prices being added for a two-to-three week period before expiration.

[8] Over time and with greater trading experience, exchanges justified rules permitting the listing of new at-the-money strike prices during the final trading days. However, the listing of additional strike prices with little time value remaining could pose customer protection issues similar to those raised by the offer of deep-out-of-the-money options. Insofar as the exchanges are required under Commission Rule 33.4(c) separately to conduct sales practice audits of member futures commission merchants concerning such practices, the Commission approved these exchange rules extending the listing of such new strike prices.

Accordingly, these codes should continue to be assigned to all existing and new accounts.

Finally, the Commission also proposed to amend Commission Rule 15.00(b)(2) which provides that the reportable level for option contracts is twenty-five contracts, except as otherwise approved by the Commission. Although the Commission has approved higher reporting levels in specific instances, it determined that in light of its surveillance experience, and to reduce the reporting burden on traders and the paperwork burden on exchanges associated with routine requests for a higher minimum level, such a higher minimum reporting level—fifty contracts—was now appropriate.

B. Comments Received

The Commission received three comments, all from futures exchanges, in response to its proposed amendments to the requirements for designation of option contracts. Two comments were generally supportive of the proposed amendments. One commenter noted that it

> commends the Commission for recognizing and responding to the realities of options trading in today's markets by proposing to eliminate unnecessary burdens contained in the existing rules and supports the proposed rule amendments and deletions primarily for the reasons set forth in the Commission's Notice of Proposed Rulemaking. In fact, the Commission's experience when exemption procedures were used to alleviate certain of the requirements now proposed to be deleted demonstrates that there will be no adverse regulatory impact from the proposals.

This commenter continued by noting with approval the specific proposals by the Commission to remove the volume requirement for designation of options on futures contracts, reasoning that "development of futures and related options markets may occur in tandem and a bright line volume test may ultimately deter the growth and development of important hedging and pricing markets." Finally, the commenter expressed strong support for the Commission's proposal to remove the requirement that exchanges provide for a period in which no new strike prices may be added before the expiration of the option.

The third commenter did not offer views regarding the specific proposed rule changes, but rather offered comments of a general nature. In this regard, the commenter "commends the Commission for undertaking this review of its contract designation requirements for options and for eliminating certain requirements while adding flexibility to others." However, this commenter contended that "[t]he full value of the proposed rulemaking will be achieved only if it results in more expeditious Commission processing of option contract proposals." The comment continued in this vein, suggesting that:

> the current contract approval process, no matter how efficiently it is administered, will always be an impediment to innovation. The requirement that there be explicit CFTC contract designation prior to launch and the ability of the CFTC to issue "materially incomplete" letters inhibits an exchange's ability to respond quickly to a market opportunity. The requirement that the contract proposal be published for public comment allows competing exchanges and off-exchange firms to copy new ideas, thus discouraging innovation.

The Commission has considered carefully these comments, and is adopting as final the proposed amendments. However, in response to the preceding comment, the Commission further notes that it is publishing separately in the **Federal Register** a request for comments on revisions to Guideline No. 1. Guideline No. 1 is the interpretative statement of the Commission which provides guidance to the exchanges on what information must be included in applications for contract market designation. The Commission anticipates that, if adopted, these proposed revisions will streamline the designation approval process by clarifying the standard of review for specified terms and conditions of proposed contract designations, reducing the required submission of unnecessary or redundant materials, and introducing a revised checklist format for the designation of options contracts. These revisions are based, in part, on the modifications hereby being promulgated by the Commission.

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires that agencies, in proposing rules, consider the impact of these rules on small entities. The Commission has previously determined that "boards of trade or contract markets" and "large traders" are not "small entities" for purposes of the RFA. 47 FR 18618 (April 30, 1982). These rules modify the requirements under which boards of trade may be designated as contract markets in options and revise the minimum reporting levels at which designated contract markets must collect information regarding the trading positions of large option traders. Accordingly, as promulgated, these rules would have no significant impact on a substantial number of small entities. For the above reasons, and pursuant to section 3(a) of the RFA, 5 U.S.C. 605(b), the Chairman, on behalf of the Commission, hereby certifies that these regulations will not have a significant economic impact on a substantial number of small entities. However, the Commission particularly invited comments from any firms or other persons which believed that the promulgation of these proposed rule amendments might have a significant impact upon their activities. No such comments were received.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1980 (Act), 44 U.S.C. 3501 *et seq.*, imposes certain requirements on federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the Paperwork Reduction Act. In compliance with the Act the Commission has submitted these amended rules and their associated information collection requirements to the Office of Management and Budget.

While these amended rules have no increased burden, the group of rules of which this is a part has the following burden:

Average Burden Hours per Response—50.34
Number of Respondents—10,727,245
Frequency of Response—Monthly

Persons wishing to comment on the estimated paperwork burden associated with these amended rules should contact Gary Waxman, Office of Management and Budget, room 3228, N.E.O.B., Washington, DC 20503. Copies of the information collection submission to OMB are available from Joe F. Mink, C.F.T.C. Clearance Officer, 2033 K Street NW., Washington, DC 20581, (202) 254-9735.

List of Subjects

17 CFR Part 5

Commodity exchange, Commodity exchange designation procedures, Commodity futures, Commodity options, Contract markets, Contract market designation fees, Dormant Contract markets, Low-volume contract markets, Low volume periods, Reporting requirement, Trading month.

17 CFR Part 15

Persons required to report, Quantities fixed for reporting.

17 CFR Part 33

Commodity exchange, Commodity exchange designation procedures, Commodity exchange rules, Commodity futures, Commodity options.

In consideration of the foregoing and pursuant to the authority contained in the Commodity Exchange Act and, in particular, sections 2(a)(1)(A), 4c(b), 4c(c), 4c(d), 4g, 4i, 5, 5a, 6 and 8a thereof, 7 U.S.C. 2, 4, 6c(a), 6c(b), 6c(d), 6g, 6i, 7, 7a, 8 and 12a, the Commission hereby amends Chapter I of title 17 of the Code of Federal Regulations as follows:

PART 5—DESIGNATION OF AND CONTINUING COMPLIANCE BY CONTRACT MARKETS

1. The authority citation for part 5 continues to read as follows:

Authority: 7 U.S.C. 6c, 7, 7a, 8 and 12a, unless otherwise noted.

§ 5.4 [Removed]

2. Section 5.4 is removed.

PART 15—REPORTS—GENERAL PROVISIONS

3. The authority citation for part 15 continues to read as follows:

Authority: 7 U.S.C. 2, 4, 5, 6a, 6c(a)–(d), 6f, 6g, 6i, 6k, 6m, 6n, 7, 9, 12a, 19, and 21; 5 U.S.C. 552 and 552(b).

4. Section 15.00 is amended by revising the section heading and paragraph (b)(2) to read as follows:

§ 15.00 Definitions of terms used in parts 15 to 21 of this chapter.

* * * * *

(b) * * *

(2) For purposes of reports regarding commodity options—

(i) For reports specified in part 16 and in § 17.01 of this chapter, any open contract position on any one contract market in the put option or separately in the call option of a specified option expiration date, which is carried on the books of any one futures commission merchant or foreign broker or which is held by a member of a contract market, and which, at the close of the market on any business day, equals or exceeds 50 options on futures contracts or 50 options on physicals, except as otherwise approved by the Commission.

(ii) For reports specified in §§ 18.00 and 18.04 of this chapter, and for recordkeeping requirements specified in § 18.05 of this chapter, 50 or more open options on futures contracts or 50 or more open options on physicals on any one contract market in a put option or separately in a call option of a specified expiration date.

* * * * *

PART 33—REGULATION OF DOMESTIC EXCHANGE-TRADED COMMODITY OPTION TRANSACTIONS

5. The authority citation for part 33 continues to read as follows:

Authority: 7 U.S.C. 2, 2a, 4, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6j, 6k, 6l, 6m, 6n, 6o, 7, 7a, 7b, 8, 9, 11, 12a, 12c, 13a–1, 13b, 19 and 21, unless otherwise noted.

6. Section 33.4 is amended by removing and reserving paragraphs (a)(5)(iii) and (b)(1)(iv), by removing paragraph (g), by removing and reserving paragraph (d)(1) and by adding paragraph (b)(2) to read as follows:

§ 33.4 Designation as a contract market for the trading of commodity options.

* * * * *

(b) * * *

(2) Prescribe an expiration date of the option that is not less than one business day before the earlier of the last trading day or the first notice day of any futures contract on the same or a related commodity; *provided, however,* that where the underlying futures contract is cash-settled, the option may expire simultaneously with the expiration of the futures contract.

* * * * *

Issued in Washington, DC, this 27th day of August, 1991, by the Commodity Futures Trading Commission.

Lynn K. Gilbert,

Deputy Secretary of the Commission.

[FR Doc. 91–21044 Filed 9–3–91; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 90F–0078]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 3,9-bis{2-[3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy]-1,1-dimethylethyl}-2,4,8,10-tetraoxaspiro[5.5]-undecane as an antioxidant in the manufacture and processing of polypropylene, complying with § 177.1520 *Olefin polymers* (21 CFR 177.1520), intended for use in contact with food. This action is in response to a petition filed by Sumitomo Chemical America, Inc.

DATES: Effective September 4, 1991. Written objections and requests for a hearing by October 4, 1991.

ADDRESSES: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 19, 1990, (55 FR 10114), FDA announced that a food additive petition (FAP 9B4164) had been filed by Sumitomo Chemical America, Inc., 345 Park Ave., New York, NY 10154, proposing that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the safe use of 3,9-bis{2-[3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy]-1,1-dimethylethyl}-2,4,8,10-tetraoxaspiro[5.5]-undecane as an antioxidant in the manufacturing and processing of polypropylene, complying with § 177.1520, intended for use in contact with food.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that the proposed use of the food additive is safe and that 21 CFR 178.2010(b) should be amended as set forth above.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before October 4, 1991 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall specify with particularly the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* *
3,9-Bis{2-[3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy]-1,1-dimethylethyl}-2,4,8,10-tetraoxaspiro[5.5]-undecane (CAS Reg. No. 90498-90-1).	For use only at levels not to exceed 0.2 percent by weight of polypropylene complying with § 177.1520(c), item 1.1 of this chapter. The finished polymer is to be used in contact with food only under conditions of use D through H described in Table 2 of § 176.170(c) of this chapter.
* * *	* *

Dated: August 23, 1991.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 91-21111 Filed 9-3-91; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 510, 520, and 529

Animal Drugs, Feeds, and Related Products; Abbott Laboratories

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the drug labeler code currently assigned to Abbott Laboratories.

EFFECTIVE DATE: September 4, 1991.

FOR FURTHER INFORMATION CONTACT: John W. Borders, Center for Veterinary Medicine (HFV-238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8737.

SUPPLEMENTARY INFORMATION: FDA has been informed by Abbott Laboratories, North Chicago, IL 60064, that it is no longer using drug labeler code "043731." Instead, the firm is currently using "000074." Accordingly, FDA is amending the regulation in 21 CFR 510.600 (c)(1) and (c)(2) to reflect the current drug labeler code. Also, the agency is amending 21 CFR 520.182(b) and 529.1526(b) to insert the current drug labeler code for Abbott Laboratories.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, and 529 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) in the entry for "Abbott Laboratories," by removing the drug labeler code "043731" and replacing it with "000074," and in the table in paragraph (c)(2) by removing the entry for "043731" and numerically adding a new entry "000074" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
Abbott Laboratories, North Chicago, IL 60064	000074
* * * *	*

(2) * * *

Drug labeler code	Firm name and address
*	* * * *
000074	Abbott Laboratories, North Chicago, IL 60064.
*	* * * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

3. The authority citation for 21 CFR part 520 continues to read as follows: