replaced with references to "Chapter X of title 31."

II. Certain Findings

Under the Administrative Procedure Act ("APA"), notice of proposed rulemaking is not required when an agency, for good cause, finds "that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."[6] The Commission is making technical amendments to Rule 17a–8 to update the reference to the BSA implementing regulations. The Commission finds that because the amendment is technical in nature and is being made solely to reflect the changes in applicable references to the BSA's implementing regulations, publishing the amendment for comment is unnecessary.[7]

The APA also requires publication of a rule at least 30 days before its effective date unless the agency finds otherwise for good cause.[8] Due to the need to coordinate the effectiveness of the amendment to Rule 17a–8 with the effective date of FinCEN's rule reorganization scheduled to take effect on March 1, 2011, and for the same reasons described above with respect to notice and opportunity for comment, the Commission finds that there is good cause for these technical amendments to take effect on March 1, 2011.

III. Consideration of Competitive Effects of Amendment

Section 3(f) of the Exchange Act,[9] provides that whenever the Commission is engaged in rulemaking and is required to consider or determine whether an action is necessary or appropriate in the public interest, the Commission shall consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. Section 23(a)(2) of the Exchange Act requires the Commission, in adopting rules under the Exchange Act, to consider the competitive effects of such rules, if any, and to refrain from adopting a rule that would impose a burden on competition not necessary or appropriate in the furtherance of the purposes of the Exchange Act.[10]

Because the amendments to Exchange Act Rule 17a–8 are technical in nature, and do not impose any additional requirements beyond those already required, we do not anticipate that the amendments would have a significant effect on efficiency, competition, or capital formation, and we do not anticipate that any competitive advantages or disadvantages would be created.

IV. Statutory Authority

We are adopting this technical amendment to Rule 17a–8 under the authority set forth in the Exchange Act, in particular, Sections 3, 10, 15, 17 and 23 thereof.[11]

List of Subjects in 17 CFR Part 240

Broker-dealers, Reporting and recordkeeping requirements, Securities.

Text of Amendments

For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 1. The authority citation for Part 240 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78l, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78ll, 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.,* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 2. Amend § 240.17a–8 by removing the phrase "part 103" in the two places it appears and adding in its place "Chapter X."

Dated: February 23, 2011.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–4694 Filed 3–1–11; 8:45 am]

BILLING CODE 8011–01–P

[6] 5 U.S.C. 553(b).

[7] For similar reasons, the amendments do not require analysis under the Regulatory Flexibility Act ("RFA") or analysis of major rule status under the Small Business Regulatory Enforcement Fairness Act. *See* 5 U.S.C. 601(2) (for purposes of RFA analysis, the term "rule" means any rule for which the agency publishes a general notice of proposed rulemaking); and 5 U.S.C. 804(3)(C) (for purposes of Congressional review of agency rulemaking, the term "rule" does not include any rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties).

[8] *See* 5 U.S.C. 553(d)(3).

[9] 15 U.S.C. 78c(f).

[10] 15 U.S.C. 78w(a)(2).

[11] 15 U.S.C. 78c, 78j, 78*o,* 78q, and 78w.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. FDA–2010–F–0200]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to permit the use of hydrogen peroxide as an antimicrobial agent in the manufacture of modified whey by ultrafiltration methods. This action is in response to a petition filed by Fonterra (USA), Inc.

DATES: This rule is effective March 2, 2011. Submit either electronic or written objections and requests for a hearing by April 1, 2011. See section VI of this document for information on the filing of objections. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of March 2, 2011.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA–2010–F–0200, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

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

Written Submissions

Submit written objections 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.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2010–F–0200 for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting objections, *see* the "Objections" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://www.regulations.gov* and insert the docket number, 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: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1282.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of April 28, 2010 (75 FR 22411), FDA announced that Fonterra (USA), Inc., c/o Burdock Group, 801 N. Orange Ave., suite 710, Orlando, FL 32801 filed a food additive petition (FAP 0A4781). The petition proposed to amend the food additive regulations in part 173—*Secondary Direct Food Additives Permitted in Food for Human Consumption* (21 CFR part 173) to provide for the safe use of hydrogen peroxide as an antimicrobial agent in the manufacture of modified whey by ultrafiltration methods. In ultrafiltration, the whey stream is directed under pressure against membranes that permit undesirable substances to pass through the membranes while retaining the whey protein.

Hydrogen peroxide is currently affirmed as generally recognized as safe (GRAS) for use as an antimicrobial agent in the preparation of modified whey by electrodialysis methods at a maximum treatment level of 0.04 percent in the whey (§ 184.1366 (21 CFR 184.1366)). As a condition of use, the regulation requires that residual hydrogen peroxide be removed from the whey during processing by appropriate chemical and physical means.

Under 21 CFR 184.1(b)(2), a substance affirmed as GRAS with specific limitations may be used in food only within such limitations, including the category of food, functional use, and level of use. Therefore, any additional uses of hydrogen peroxide in processing food beyond those limitations set out in § 184.1366 requires either a food additive regulation or an amendment of § 184.1366. The current petition proposes to amend the food additive regulations to provide for the use of hydrogen peroxide in the preparation of modified whey by ultrafiltration methods, as an alternative to electrodialysis methods, at a maximum use level of 0.001 percent by weight of the whey, providing that residual hydrogen peroxide is removed from the whey during processing by appropriate chemical and physical means.

II. Conclusion

FDA reviewed data in the petition and other available relevant material to evaluate the safety of the use of hydrogen peroxide as an antimicrobial agent in the production of modified whey prepared by ultrafiltration methods. Based on this information, the Agency concludes that the proposed use of the additive will accomplish the intended technical effect, and that, since the proposed use of hydrogen peroxide in the preparation of modified whey by ultrafiltration would be substitutional for its already-regulated use in the preparation of modified whey by electrodialysis under § 184.1366, the exposure to hydrogen peroxide will not increase and may potentially decrease due to a lower maximum use level than what is currently permitted in the manufacture of modified whey by electrodialysis. Based on this information, FDA concludes that the proposed use of the additive is safe and the additive will achieve its intended technical effect as an antimicrobial agent under the proposed conditions of use. Therefore, the regulations in 21 CFR part 173 should be amended as set forth in this document.

III. Public Disclosure

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 will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (*see* **FOR FURTHER INFORMATION CONTACT**). As provided in § 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.

IV. Environmental Impact

The Agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 0A4781 (75 FR 22411). No new information or comments have been received that would affect the Agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written objections by (*see* **DATES**). Each objection shall be separately numbered, and each numbered objection shall specify with particularity 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. It is only necessary to send one set of documents. It is no longer necessary to send three copies of all documents. Identify documents 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

FDA's review of this petition was limited to section 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(ll) (21 U.S.C. 331(ll)). Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been

instituted and their existence has been made public, unless one of the exceptions in section 301(ll)(1) to (ll)(4) applies. In our review of this petition, FDA did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

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 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Section 173.356 is added to subpart D to read as follows:

§ 173.356 Hydrogen peroxide.

Hydrogen peroxide (CAS Reg. No. 7722–84–1) may be safely used to treat food in accordance with the following conditions:

(a) The additive meets the specifications of the *Food Chemicals Codex,* 7th ed. (2010), pp. 496 and 497, which is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal regulations/ibr_locations.html.*

(b) The additive is used as an antimicrobial agent in the production of modified whey (including, but not limited to, whey protein concentrates and whey protein isolates) by ultrafiltration methods, at a level not to exceed 0.001 percent by weight of the whey, providing that residual hydrogen peroxide is removed by appropriate chemical or physical means during the processing of the modified whey.

Dated: February 16, 2011.

Susan M. Bernard,

Acting Director, Office of Regulations, Policy and Social Services, Center for Food Safety and Applied Nutrition.

[FR Doc. 2011–4497 Filed 3–1–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 558

[Docket No. FDA–2011–N–0003]

Animal Drugs, Feeds, and Related Products; Withdrawal of Approval of a New Animal Drug Applications; Phenylbutazone; Pyrantel; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations by removing those portions that reflect approval of eight new animal drug applications (NADAs). In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of these NADAs.

DATES: This rule is effective March 14, 2011.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9079, *e-mail: john.bartkowiak@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The sponsors have requested that FDA withdraw approval of the three NADAs listed in table 1 of this document because the products are no longer manufactured or marketed:

TABLE 1—VOLUNTARY REQUESTS FOR WITHDRAWAL OF APPROVAL OF THREE NADAS

Sponsor	NADA No. product (established name of drug)	21 CFR section affected (sponsor drug labeler code)
First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123	NADA 48–647; Phenylbutazone Boluses (phenylbutazone).	§ 520.1720a (058829).
Yoder Feed, Division of Yoder, Inc., Kalona, IA 52247 ...	NADA 96–161; Hy-Con TYLAN Premix (tylosin phosphate).	§ 558.625 (035369).
Triple "F", Inc., 10104 Douglas Ave., Des Moines, IA 50322.	NADA 119–062; Cadco-BN-10 BANMINTH Premix (pyrantel tartrate).	§ 558.485 (011490).

Truow Nutrition, Inc., 1590 Todd Farm Dr., Elgin, IL 60123 (Truow) has informed FDA that it is the owner of five feed premix NADAs previously owned by milling companies which it has purchased. NADA 100–352 was owned by NutriBasics Co., last doing business at P.O. Box 1014, Wilmar, MN 56201. NADA 107–002 and NADA 123–000 were owned by Seeco, Inc., also last doing business at P.O. Box 1014, Wilmar, MN 56201. NADA 133–833 and NADA 135–243 were owned by Southern Micro-Blenders, Inc., last doing business at 3801 N. Hawthorne St., Chattanooga, TN 37406. Truow has requested that FDA withdraw approval of the five NADAs in table 2 of this document because they are no longer manufactured or marketed: