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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1170

RIN 0581-AC66

[Doc. #AMS-DA-07-0047; DA-06-07]

Dairy Product Mandatory Reporting

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule adopts amendments to the Dairy Product Mandatory Reporting Program that was established on August 2, 2007 on an interim final basis. The Dairy Market Enhancement Act of 2000, and certain provisions of the Farm Security and Rural Investment Act of 2002, amended the Agricultural Marketing Act of 1946 to provide for timely, accurate, and reliable market information to facilitate more informed marketing decisions and promote competition in the dairy product manufacturing industry.

DATES: *Effective Date:* June 22, 2008.

FOR FURTHER INFORMATION CONTACT: For information relevant to this final rule: (a) Concerning dairy product price data collection, reporting and verification contact John R. Mengel, Chief Economist, USDA/AMS/Dairy Programs, Office of the Chief Economist, STOP 0229-Room 2753, 1400 Independence Ave., SW., Washington, DC 20250-0229, (202) 720-4664; (b) concerning dairy products storage data collection and reporting contact Dan Kerestes, Chief, Livestock Branch, USDA/NASS, STOP 2053-Room 6435, 1400 Independence Ave., SW., Washington, DC 20250-2053, (202) 720-3570.

SUPPLEMENTARY INFORMATION: This final rule is a statutory requirement pursuant to the Agricultural Marketing Act of 1946 [7 U.S.C. 1621 *et seq.*], as amended

November 22, 2000, by Public Law 106-532, 114 Stat. 2541, and further amended May 13, 2002, by Public Law 107-171, 116 Stat. 207. The Agricultural Marketing Act of 1946 and its amendments are hereinafter referred to as the "Act."

The provisions of the interim final rule were published in the **Federal Register** on July 3, 2007 (72 FR 36341), and became effective on August 2, 2007. The interim final rule states that comments were to be submitted on or before September 4, 2007. On November 2, 2007, a **Federal Register** notice was issued to reopen the comment period whereby comments were to be submitted on or before December 3, 2007 (72 FR 62105). The U.S. Department of Agriculture (USDA) has reviewed and considered all of the comments submitted in a timely manner for this final rule.

Background: The Act provides for and accordingly, the interim final rule established, a Dairy Product Mandatory Reporting Program that: (1) Requires persons engaged in manufacturing dairy products to provide to USDA certain information including the price, quantity, and moisture content, where applicable, of dairy products sold by the manufacturer; and (2) requires manufacturers and other persons storing dairy products to report to USDA information on the quantity of dairy products stored. Under the interim final rule, the National Agricultural Statistics Service (NASS) collects such information. This final rule, in accordance with the Act, maintains these requirements. Any manufacturer that processes and markets less than 1 million pounds of the applicable dairy products per calendar year is exempt from these reporting requirements as specified in (1) of this paragraph.

NASS began publishing cheddar cheese price data in 1997. It began publishing butter, nonfat dry milk (NFD), and dry whey price data in 1998. Currently, NASS publishes cheddar cheese, butter, dry whey, and NFD prices on a weekly basis. USDA has collected and reported stock data on a voluntary basis for butter and cheese since 1916, for NFD since 1930, and for dry whey since 1975. Stock information on specific cheeses, salted and unsalted butter, anhydrous milkfat, butter oil, nonfat dry milk and dry whey

is now collected and published on a monthly basis.

The Act, as amended, provides USDA with the authority needed to make the reporting of dairy product price and stock information mandatory. No additional commodities are included under this rule. The Act also provides that USDA shall take such actions as it considers necessary to verify the accuracy of the information submitted or reported. With more complete and accurate information, USDA and the dairy industry can be confident that reported dairy product prices and inventories are more precise indicators of supply and demand conditions.

The Agricultural Marketing Service (AMS) has implemented a plan to verify the price information submitted by reporting entities to NASS. Each reporting entity may report for a single dairy plant or it may report for more than one dairy plant, depending upon how the business is structured. During the first year of verification, AMS planned to visit all of the reporting entities eligible to file reports at least once. AMS visited all of the reporting entities within the first five months of implementation. In subsequent years, AMS plans to visit larger entities that account for 80 percent of the yearly reported product volume of each specified dairy product at least once annually. AMS plans to visit one-half of entities that account for the remaining 20 percent each year, visiting each such entity at least once every other year.

During each visit, AMS will review applicable sales transactions records for at least the four most recent weeks. In some cases AMS may review sales records for longer periods of up to 2 years. AMS will verify that sales transactions agree with information reported to NASS and that there are no applicable sales transactions that are not reported to NASS. This final rule includes noncompliance, appeals, and enforcement procedures. These procedures are carried out by AMS.

AMS requested comments on all aspects of the reporting requirements, the reporting specifications, and the verification program. AMS has reviewed all timely comments received and has considered these comments in developing this final rule.

Executive Order 12866: Regulatory Planning and Review

This final rule has been determined not to be "significant" for purposes of Executive Order 12866 and therefore has not been reviewed by the Office of Management and Budget. A cost benefit analysis prepared for the interim final rule is available at <http://www.ams.usda.gov/dairy/>.

Executive Order 12988: Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have a retroactive effect. This rule will not preempt any State or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of this rule.

Regulatory Flexibility Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS considered the economic impact of this final rule on small entities and determined that the rule would not have a significant economic impact on a substantial number of small entities. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened.

Small businesses in the dairy product manufacturing¹ industry have been defined by the Small Business Administration (SBA) as those processors employing not more than 500 employees. For purposes of determining a processor's size, if the plant is part of a larger company operating multiple plants that collectively exceed the 500-employee limit, the plant will be considered a large business even if the local plant has fewer than 500 employees. There are approximately 98 dairy product manufacturers and 110 manufacturers and other persons storing dairy products that would be subject to the provisions of this rule. According to U.S. Census Bureau Statistics of U.S. Businesses, there were 1,110 dairy manufacturing firms in the United States in 2004. Of these businesses, 1,017 firms had fewer than 500 employees and 93 firms had greater than 500 employees.

Therefore, few of the manufacturers and persons affected by this final rule are small businesses under the criteria

established by the SBA. Those manufacturers that process and market less than 1 million pounds of the applicable dairy products annually are exempted from price reporting by this final rule, and most of the entities that would be subject to mandatory reporting already report this information to NASS. The annual cost to manufacturers reporting product prices is estimated at \$381 per plant. As discussed in the Paperwork Reduction Act section below, AMS believes the records that would be required to be maintained under this final rule are already being maintained for at least 2 years as part of the normal course of business. Thus, there would be no additional burden or cost associated with the maintenance of these records. Therefore, the final rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (44 U.S.C. Chapter 35), reporting and recordkeeping requirements that are utilized to collect the information required by the Act have been approved by the Office of Management and Budget (OMB). The OMB control number for the Dairy Products Prices questionnaire and the Dairy Products questionnaire is 0535–0020. The OMB control number for the Cold Storage questionnaire is 0535–0001.

The primary function of NASS is to provide timely, accurate, and useful statistics in service to U.S. agriculture. Estimates of milk production, production and storage of manufactured dairy products, and prices of milk and dairy products are integral parts of this function. Milk and dairy statistics are used by USDA to help administer Federal programs and are used by the dairy industry in planning, pricing, and projecting supplies of milk and milk products.

Neither the interim final rule nor this final rule changes the current method and frequency of data collection utilized by NASS. Data collection of Dairy Products Prices is conducted weekly to collect sales transactions data for the previous week. Manufacturers are provided a supply of report forms for the products they are to report. The dairy product manufacturer completes the forms with information, including the manufacturer's name, address, plant location, quantities sold, and prices (or dollars received) for cheddar cheese, butter, dry whey, and NFDM. Manufacturers report to NASS by facsimile or electronic data reporting.

The monthly Dairy Products questionnaire is mailed each month to manufacturers of dairy products. Manufacturers report to NASS the name, address, production, stocks, and shipments data for a wide variety of dairy products, including nonfat dry milk and dry whey. Reporting entities report to NASS by facsimile, phone, or mail.

The monthly Cold Storage questionnaire is mailed each month to manufacturers and other entities storing stocks of a wide variety of refrigerated agricultural commodities, including butter, cheese, and similar products. Manufacturers and other entities report to NASS the name, address, and stocks on hand at the end of the month. Reporting entities report to NASS by facsimile, phone, mail, or electronic data reporting.

This final rule continues implementation of recordkeeping requirements established under the interim final rule and authorized by the Act. Under this regulation, each person required to report information to USDA shall maintain, and make available to USDA, on request, original contracts, agreements, receipts, and other records associated with the sale or storage of any dairy products during the 2-year period beginning on the date of the creation of the records. AMS has consulted with several entities that are required to maintain records under this rule. According to the entities consulted, the necessary records are already being maintained for at least 2 years as part of the normal course of business. Therefore, there would be no additional burden or cost associated with the maintenance of these records.

The reliability of prices announced by NASS is dependent on the accuracy of the reports submitted by manufacturers. To verify that the data submitted to NASS for the Dairy Products Prices report is accurate, all manufacturers required to submit questionnaires will be subject to a verification procedure conducted by AMS. Failure on the part of manufacturers or other entities to comply with the data collection and recordkeeping requirements could lead to enforcement action, including the levying of civil penalties provided under section 273 of the Act, as amended [7 U.S.C. 1637b], against the violating person or entity.

Except as otherwise directed by the Secretary of Agriculture or the U.S. Attorney General for enforcement purposes, no officer, employee, or agent of the United States shall make available to the public information, statistics, or documents obtained from or submitted by any person under the Act other than

¹ North American Industry Classification System (NAICS) code 3115.

in a manner that ensures confidentiality is preserved regarding the identity of persons, including parties to a contract and proprietary business information. All report forms include a statement that individual reports are kept confidential.

With respect to the application of the Privacy Act of 1974 (5 U.S.C. 552a) to the maintenance of records required by the Act, the Dairy Products Prices survey population consists of agribusinesses. Data collected by this survey relates to agribusinesses' dealings and not those of individuals. Records maintained at business sites for verification of information reported to NASS include contracts, agreements, receipts and other material related to sales of specific dairy products. No records about individuals are maintained by NASS for this survey, and AMS believes that none would be part of these maintained business papers.

Summary of Changes in the Final Rule From the Interim Final Rule

All substantive changes in this final rule from the interim final rule concern reporting requirements and specifications pertaining to the Dairy Products Prices report. Changes are as follows:

(1) Products that are produced under faith-based close supervision and are marketed at a higher price than the manufacturer's wholesale market price for the basic commodity (for example, kosher products produced with a rabbi on site who is actively involved in supervision of the production process) are excluded in the reporting specifications.

(2) With the interim final rule, dairy products sold under the Dairy Export Incentive Program (DEIP) were included in the reporting specifications. DEIP sales or other premium-assisted sales are excluded in reporting specifications with this final rule.

(3) Products certified as organic by USDA-accredited certifying agents are excluded in the reporting specifications with this final rule.

(4) With the interim final rule the grade requirements stated that each product to be reported was to be of a certain grade. The final rule indicates that each product to be reported must only meet certain grade standards.

(5) The interim final rule indicates that transportation charges are to be excluded from the reported price for each commodity. The final rule clarifies that each sale shall be reported either f.o.b. plant if the product is "shipped out" from the plant or f.o.b. storage facility location if the product is

"shipped out" from a storage facility. In calculating the total dollars received or dollars per pound, the reporting entity shall neither add transportation charges incurred at the time the product is "shipped out" or after the product is "shipped out" nor deduct transportation charges incurred before the product is "shipped out."

(6) The interim final rule excludes clearing charges in the reporting specifications. The final rule specifies that in calculating the total dollars received or dollars per pound, the reporting entity shall not deduct brokerage fees or clearing charges paid by the manufacturer.

(7) This final rule specifies that the verification and noncompliance procedures are pursuant to section 273(b)(1)(A)(i) of the Act.

(8) This final rule specifies the time by which dairy product manufacturers must report on all dairy products sold. Manufacturers must report by noon on Wednesday on all products sold during the seven days ending with the previous Saturday.

(9) Changes have been made in the organization or content of some sections for greater clarity.

Discussion of Comments

The interim final rule solicited comments to be submitted to USDA on or before September 4, 2007. During this initial 60-day comment period, 19 comment submissions were received: 6 from dairy cooperative associations, 4 from federations of dairy cooperative associations, 3 from producer associations, 3 from proprietary dairy manufacturers, 1 from a dairy manufacturer association, and 2 from individuals. After reviewing comments received, USDA determined that additional information from interested parties would be helpful. On November 2, 2007, a **Federal Register** notice was issued to reopen the comment period for an additional 30 days. USDA specifically solicited comments concerning the issues of product specifications, minimum transaction volumes, kosher dairy products, and products produced from cows not treated with recombinant bovine somatotropin (rBST). USDA was concerned that for the initial comment period some commenters may have limited their comments to the issues of forward-priced contracts and verification. During the extended 30-day comment period, 10 comment submissions were received: 2 from dairy cooperative associations, 2 from federations of dairy cooperative associations, 1 from a producer association, 1 from a dairy manufacturer

association, and 4 from individuals. USDA has reviewed and considered all of the comments submitted in a timely manner for this final rule.

The following discussion is based upon USDA consideration of all comments received concerning the interim final rule and other considerations. The discussion concerns reporting requirements and specifications for the Dairy Products Prices survey.

1. Forward-Priced Contracts

Under the interim final rule, forward pricing sales (sales in which the selling price was set [not adjusted] 30 or more days before the transaction was completed) are excluded from reporting specifications.

The issue of forward-priced contracts is the issue discussed at greatest length and by the greatest number of commenters. All comments concerning the issue focus upon sales of nonfat dry milk (NFDM). None of the commenters argues for including forward-priced contracts in the reporting specifications for the other dairy products.

Positions taken by commenters on the issue are essentially as follows:

a. Include forward-priced contracts for NFDM.

b. Include contracts for export sales of NFDM that are shipped within 90 days of contract execution.

c. Include contracts for domestic or export sales of NFDM that are shipped within 90 days of contract execution.

d. Make no changes.

e. In addition to excluding forward-priced contracts for which the selling price is set 30 or more days before the transaction was completed from reporting specifications, also exclude contracts that reference a defined prices series, plus or minus a basis, entered into more than 30 days before delivery.

Supporters of including forward-priced contracts in NFDM price reporting argue that the current exclusion of forward-priced contracts discourages exports because almost all NFDM exports are through contracts with shipments more than 30 days after execution. Therefore, the vast majority of export sales are excluded from NASS reporting. DairyAmerica, Inc., states, "The proposed NASS sample that leaves out critical supply and demand for milk represented by the export market raises the question of 'unbiasedness'. * * * " DairyAmerica contends that if fixed-priced contracts were included in the reporting requirements, Class IV milk prices would more closely align with the majority of sales of NFDM. It claims that this would reduce risks for NFDM producers. It points out that there is no

effective futures market for NFDm at this time. Other supporters of including forward-priced contracts in NFDm price reporting include California Dairies, Inc., and the Alliance of Western Milk Producers.

Fonterra Co-operative Group Limited provides a discussion of contracts used for the international dairy market. Fonterra points out that due to certification procedures, regulatory requirements, etc., a seller in the international market does not have complete control of the timeframe for delivery. Fonterra describes spot, medium-term, and long-term export contracts. An export contract for "immediate" delivery can take 1 to 2 months to complete. A medium-term contract typically covers 3 months but usually takes about 5 months from the time of contract to the time of the last invoice date. A long-term contract is typically for 6 months but may be as long as 12 months.

National Milk Producers Federation (NMPF) advocates extending the time period of reporting NFDm sales from 30 days to 90 days in recognition of growth of NFDm exports and the requirements for export sales. NMPF notes that effective and liquid futures contracts exist for Class III milk (which are often used as hedge instruments for cheese prices) and butter. However, the same is not the case for NFDm. The extension of the time period as proposed by NMPF would only apply to export contracts. NMPF states that limiting the reporting time period to 90 days will ensure that forward-priced export contracts do not have a disproportionate effect on Federal order pricing. Land O'Lakes, Inc., (LOL) and DairyLea Cooperative, Inc., support NMPF's position. Western United Dairymen also proposes extending the time of reporting from 30 to 90 days, but it does not specify that the extension would apply to exports only.

Supporters of the current 30-day limit assert that the current policy better reflects the current market price. International Dairy Foods Association (IDFA) states, "The inclusion of sales in which the price was set more than 30 days in advance of the actual transaction would mean including survey data based on expectations of today's market environment, not the actual current market environment itself." Dean Foods contends that including forward-priced contracts could result in a market distortion related to Class II products. According to Dean Foods, at times it may be advantageous to manufacture Class II products from NFDm rather than from Class II milk since the spot NFDm price

in the domestic market place would not necessarily be in alignment with the Class IV price or Class II price. With respect to NFDm futures markets, Leprino Foods Company states, "Although there are likely additional factors, we believe that the historic practice of certain nonfat manufacturers of including long-term contracts in prices reported and used in establishing the underlying milk prices have substantially limited the establishment of viable nonfat dry milk futures." Other supporters of the current regulation include Nestlé USA and an individual commenter.

Dairy Producers of New Mexico (DPNM) advocates the current 30-day limit reporting exclusion and also the exclusion of forward contracts that reference a defined price series plus or minus a basis. It contends that inclusion of such contracts in reporting leads to circularity in pricing and does not provide accurate information concerning spot prices for dairy products.

This final rule maintains the current reporting exclusion for forward pricing sales (sales in which the selling price was set [not adjusted] 30 or more days before the transaction was completed). IDFA's argument has merit: "The inclusion of sales in which the price was set more than 30 days in advance of the actual transaction would mean including survey data based on expectations of today's market environment, not the actual current market environment itself."

This final rule does not exclude from reporting specifications forward contracts that reference a defined price series plus or minus a basis. Information is not readily available to indicate that there is any significant problem with bias caused by circularity in the reporting of such forward contracts.

2. *Electronic Data Collection by AMS*

NMPF lists reasons as to why AMS, rather than NASS, should have full responsibility for mandatory dairy product reporting. According to NMPF, AMS is better suited for regulatory enforcement, and AMS staff is better equipped to collect and verify consistent data from milk plants. NMPF states that AMS staff employees generally have more dairy expertise and usually have longer tenure than NASS employees. NMPF believes that coordination of the data collection and the verification would be improved if AMS handled both functions. Since AMS has experience with electronic reporting through its mandatory livestock reporting program, NMPF asserts that AMS is better suited to

implement electronic reporting for dairy products.

IDFA also asserts that AMS should be responsible for data collection and that the data should be collected electronically. IDFA contends that if AMS were to collect the data electronically at a national level, timeliness of reporting would be improved and conflicting information from NASS offices in different States would be eliminated. DairyLea Cooperative also advocates that AMS collect the data electronically.

This rule makes no changes with respect to responsibilities or methods for data collection. The Secretary of Agriculture has delegated NASS, an agency with data collection as its primary mission, as the USDA agency with price reporting responsibilities for the Mandatory Dairy Product Reporting Program.

3. *More Frequent Verification*

New York Farm Bureau is concerned that the frequency of verification visits in the proposed rule may not be sufficient to guarantee accurate and timely verification. It does not propose a specific time period for the frequency of visits. IDFA supports the AMS plan to visit all of the entities eligible to file reports at least once during the first year. However, it urges AMS to follow up with quarterly visits to any entities that have been found to have reported incorrectly.

AMS planned to visit all entities eligible to report in the first year at least once. AMS visited all of the reporting entities within the first five months of the Mandatory Dairy Product Reporting Program implementation. Some reporting entities have been visited more than once. AMS plans to visit large entities that account for 80 percent of the yearly reported product volume of each specified dairy product at least once annually. AMS plans to visit one-half of the remaining entities each year, visiting each such entity at least once every other year. This does not preclude additional visits if necessary.

4. *Organic Product Exclusion*

IDFA, NMPF, and Dean Foods propose that organic products be excluded from the surveys because they receive higher wholesale market prices reflecting additional costs that are not representative of the products in the broader market. Dean Foods is more specific than IDFA or NMPF, stating that "Certified Organic" products should be excluded. No comments were received advocating the inclusion of organic products in price reporting.

This final rule excludes products certified as organic by USDA-accredited certifying agents in the reporting specifications because such products command higher prices, reflecting consumers' perception that such products are of higher value than similar products.

5. *Coordination of Price Reporting With the California Department of Food and Agriculture (CDFA)*

Both NMPF and DairyAmerica encourage USDA to take steps to align price data, methodology, and timing with that of CDFA. While NMPF encourages broad cooperation with CDFA concerning alignment of all class prices, DairyAmerica's comments are limited to considerations of NFDN price reporting.

DairyAmerica's submission of comments includes testimony from a recent CDFA hearing concerning NFDN price reporting. CDFA conducted a public hearing on August 28, 2007, to consider revisions to weekly and monthly NFDN price reporting for the California Weighted Average Price (CWAP). On October 17, 2007, CDFA issued a final decision regarding the CWAP (http://www.cdffa.ca.gov/dairy/dairy_hear_finalresults_Aug07.html). The decision became effective on October 26, 2007.

AMS has reviewed testimony from the CDFA hearing in its deliberations for this final rule. As DairyAmerica acknowledges, " * * * AMS cannot simply agree to operate its system based upon California." USDA must make decisions based upon its own program objectives, consideration and judgment of the issues, and comments.

6. *Transaction-Size Thresholds*

The typical sales unit for dairy products included in the Dairy Products Prices survey is 40,000 pounds. IDFA recommends setting a transaction-size threshold of 40,000 pounds for products to be reported for the Dairy Products Prices survey. It points out that dairy contracts for the Chicago Mercantile Exchange (CME) are based upon this typical size unit. Similarly, NMPF proposes that USDA set transaction-size thresholds for reporting sales, claiming that products distributed in smaller lots have added value and cost. However, NMPF states that any decision to establish transaction thresholds should be considered very carefully to ensure that no important product volumes are omitted from reporting and to avoid efforts by manufacturers "to reorganize distribution to evade reporting." NMPF suggests that USDA consider a threshold

of 30,000 pounds for each product included in the survey.

USDA has not included transaction-size thresholds in this final rule. An objective of the survey is to obtain a broad measure of basic dairy commodity prices across the U.S. There is concern that a significant number of plants may be excluded from reporting if thresholds are established. Also, there is concern, as expressed by NMPF, that some reporting entities could "reorganize distribution to evade reporting." Furthermore, adding transaction-size thresholds to the reporting specifications could add an unnecessary reporting burden for some reporting entities due to the necessity of keeping separate sales totals for transactions that meet thresholds and those that do not.

7. *High-Heat and Fortified NFDN*

According to LOL, the costs and pricing arrangements for high-heat NFDN closely resemble those of low-heat and medium-heat NFDN. LOL asserts that including high-heat NFDN in the reporting specifications would result in greater alignment with the CWAP. DairyAmerica also proposes including high-heat NFDN in the reporting specifications and also would include fortified NFDN.

This final rule continues exclusions for high-heat and fortified NFDN in the reporting specifications. Observation of prices reported in USDA Dairy Market News indicates that prices for high-heat NFDN are generally higher than those for low and medium-heat NFDN. Adding value to NFDN through fortification also would result in a higher price generally than that of the basic commodity.

8. *Dairy Export Incentive Program (DEIP) or Other Premium-Assisted Sales*

DairyAmerica claims that DEIP sales should continue to be reported, asserting that excluding DEIP sales in the reporting specifications would be in conflict with the policy decision of Congress to support exports with taxpayer dollars. DairyAmerica claims that if DEIP sales were to be excluded from the reporting specifications, prices paid for milk through the Federal order system would not be reflective of the commodity prices of products sold through DEIP. This situation increases the risk that the manufacturers engaged in DEIP sales will suffer loss. For the same reasons, DairyAmerica asserts that export assistance sales through the voluntary industry program, Cooperatives Working Together (CWT) program, should be reported.

Leprino asserts that the timeliness criteria for reporting DEIP sales should

be the same as for any other dairy products that meet the reporting specifications. It asserts the same rationale as for other sales: DEIP sales for which the sale price was established greater than 30 days prior to ship date may not be reflective of current market conditions.

With this final rule, all DEIP sales or other premium-assisted sales, such as export assistance sales through the CWT program, are excluded from the reporting specifications. Before mandatory reporting became effective, DEIP sales were included in reporting specifications to encourage voluntary reporting by manufacturers that wanted DEIP sales to be included. Since reporting is now mandatory, this is no longer a consideration. As pointed out by Leprino, DEIP contracts entered into more than 30 days before date of shipment may not be reflective of current market conditions. Furthermore, DEIP sales or other premium-assisted sales include bonuses paid by third parties. Export bonuses are frequently based upon market averages of domestic and international commodity prices that may or may not be reflective of the actual needs of the two parties to reach a sales agreement.

9. *Commodity Credit Corporation (CCC) Purchases Under the Milk Price Support Program and Related Programs*

DairyAmerica asserts that CCC sales must continue to be reportable in order to avoid the risk that Federal order minimum prices would fall below support levels.

CCC purchases under the Milk Price Support Program and related programs continue to be included in the reporting specifications under this final rule. Including CCC purchases provides a broader survey that more accurately reflects market conditions.

10. *Intra-Company Sales*

Reporting specifications exclude intra-company sales. DairyAmerica supports this policy in general because such sales may not represent a true market price. However, DairyAmerica asserts that its sales, as a federation of dairy cooperatives, between a member and that member's wholly-owned subsidiary should be reportable. It argues that these sales are arms-length transactions. DairyAmerica states that its corporate structure requires it to maximize revenue for its members and that it cannot favor one member of the federation over another.

This final rule continues the exclusion of intra-company sales, even if those sales are to wholly-owned subsidiaries through a federation of

dairy cooperatives. Although a federation of dairy cooperatives may have rules that all sales will be at market prices, it may not be possible to verify through the federation and manufacturer books and records that such intra-company sales are arms-length transactions.

11. Enforcement

DPNM asserts that manufacturers who misreport to NASS should have greater liability than stated in the interim final rule. DPNM proposes that a handler that misreports prices be held responsible to account to various producer settlement funds for any shortfalls that occur due to the misreporting. Dairylea proposes that USDA be held responsible for shortfalls in dairy producer income that result from misreporting of prices.

The Act is clear concerning the civil penalty for noncompliance with a cease and desist order relative to specified unlawful acts. The Act states, "If the [district] court finds that the person violated the order, the person shall be subject to a civil penalty of not more than \$10,000 for each offense." Since the Act does not provide for the redress proposed by either DPNM or Dairylea, this final rule does not include the enforcement proposals by DPNM or Dairylea.

12. Products Labeled or Contracted as Sourced From Cows Not Treated With Recombinant Bovine Somatotropin (rBST):

NMPF lists reasons that it believes products sourced from milk from cows not treated with rBST should be included in reporting specifications. According to USDA Animal and Plant Health Inspection Service, only 15 percent of dairy herds include cows treated with rBST. Many products are made from such milk even if not marketed as such. Marketing of such products is increasing, and NMPF asserts that excluding them would compromise the survey. Manufacturers may have mixed sales (some from cows treated with rBST and some with cows not treated with rBST), complicating reporting and verification. Furthermore, NMPF claims that it would be inappropriate for USDA to define, categorize, and verify labeling of such products.

Three individuals submitted comments in support of including products labeled or contracted as sourced from cows not treated with rBST in the reporting specifications. Two of the individuals assert that excluding such products would undervalue milk prices paid to dairy farmers.

LOL urges AMS to exclude products labeled as sourced from cows not treated with rBST in the reporting specifications. LOL claims that producers who discontinue using rBST have a significant drop in milk production, and it claims that the opportunity costs of discontinuing use of rBST are \$1.00 to \$1.50 per hundredweight. Therefore, LOL asserts that these producers should receive premiums. Excluding such products would in part help to share these premiums with only those producers who forego the benefits of using rBST. In the future, if products labeled as sourced from cows not treated with rBST become more common, LOL would support including such products in the surveys.

IDFA urges USDA to exclude products labeled or contracted as sourced from cows not treated with rBST, claiming that such products are value-added products rather than commodity products.

The final rule does not exclude products labeled or contracted as sourced from cows not treated with rBST. Further, USDA does not have information to indicate that there are substantial price premiums for such products, and the sales volumes of such products are unknown.

13. Kosher Products

NMPF points out that nearly all butter and nonfat dry milk, and most dry whey production is kosher, by some standard. The same can be said for a substantial amount of cheese. NMPF asserts that there are many kosher standards and that it would be improper for USDA to rule based upon those standards. LOL and two individual commenters support including all kosher products in the reporting specifications.

DairyAmerica advocates a very narrow exclusion of only a specially supervised form of kosher designated as "Cholov Yisroel," a kosher designation that requires close rabbinical supervision from the farm through the dairy product manufacturing process. It states that this type of kosher product should not be reportable, or the extra cost element for this type of kosher designation should be deducted. IDFA urges USDA to exclude kosher products from the reporting specifications if the contract requires the products to be certified as kosher under direct rabbinical supervision.

Since the final rule is concerned with capturing prices for basic commodities, it attempts to exclude value-added products from the price surveys. For kosher products, care is taken in the final rule to use a standard that is

neither too broad nor too narrow. Excluding all products meeting the least stringent kosher standards would be too broad since such products are commonplace and the added market value is insignificant. This final rule only excludes products manufactured under close rabbinical supervision and marketed at a higher price than the manufacturer's wholesale market price for the basic commodity.

It is possible that reporting issues will arise concerning dairy products that are manufactured to meet certain faith-based standards other than kosher requirements. For example, Islamic Halal has certain production requirements for dairy products. For this reason, this final rule excludes any dairy products produced under any faith-based close supervision that are marketed at a higher price than the manufacturer's wholesale market price for the basic commodity.

14. Cost Add-Ons

Dairylea proposes that "AMS allow for dairy product manufacturing cost of production surcharges—determined through a regulated process—to be reported in the pricing survey. These USDA determined cost increases should be allowed to be passed on from a manufacturer to the marketplace, without it impacting the Federal Order class prices."

Consideration of Dairylea's cost add-ons proposal in this informal rulemaking is not appropriate. Dairylea provided the same proposal in its testimony at a hearing concerning Class III and IV prices (Federal milk marketing order hearing; Indianapolis, Indiana; April 11, 2007, Tr. page 1966; exhibit 53). USDA is considering Dairylea's proposal in formal rulemaking with respect to that hearing.

15. Expansion of the Scope of Data Collection and Reporting

DPNM proposes that the Dairy Product Mandatory Reporting Program be expanded to include the volume of milk and milk components acquired by the plant, the prices paid for milk and milk components acquired by the plant, the volume of milk products produced at the plant, the value of the milk products produced at the plant, and, alternatively, the costs and yields associated with making reported products.

DPNM proposes that these items be collected and reported in order to help USDA make better decisions with respect to make allowances and yield factors. DPNM notes that the Act uses the phrase "information concerning the price, quantity, and moisture content of

dairy products” in the description of information to be obtained. Using a broad perspective of the word “concerning,” DPNM asserts that USDA has authority to collect the additional information proposed.

This final rule does not add data collection as proposed by DPNM. Collection of such information is beyond the scope of the Act.

16. *Product f.o.b. Points*

The interim final rule states that sales shall be reported f.o.b. processing plant or storage location. Leprino claims that pricing f.o.b. storage center is inappropriate because such pricing results in a price with a different location value than that of the plant. It further claims that costs to ship products to storage centers are not included in Federal order make allowance calculations; therefore, such costs should not be included in the survey prices. It proposes that the price reported should be reduced by the cost of transporting products to storage centers.

With this final rule, AMS continues the policy of requiring sales to be reported f.o.b. reporting plant or storage center without adjustment for transportation to storage facilities prior to sale. While pricing f.o.b. storage center may reflect a location value that is different than that which exists at the manufacturing plant, reducing the price by some unspecified transportation cost, which may or may not be consistent with the product value, is inappropriate. The pricing at f.o.b. storage facility would presumably be competitive with prices of competitors in the surrounding area. Reporting a price reduced by the transporting of the product to the storage center may understate the wholesale value of the product at that location and time.

The interim final rule indicates that transportation charges are to be excluded from the reported price for each commodity. This exclusion is not intended to apply to transportation costs from the manufacturer to a storage facility before the product is sold. The final rule clarifies that each sale shall be reported either f.o.b. plant if the product is “shipped out” from the plant or f.o.b. storage facility location if the product is “shipped out” from a storage facility. In calculating the total dollars received or dollars per pound, the reporting entity shall neither add transportation charges incurred at the time the product is “shipped out” nor deduct transportation charges incurred before the product is “shipped out.”

17. *Grade A Dry Whey*

Leprino states that Grade A dry whey should continue to be excluded because it is a premium product. This final rule agrees and continues the exclusion for Grade A dry whey.

18. *Inclusion of Products That Are Not Graded*

Questions have arisen concerning the reporting of products that are not graded by authorities stated in the reporting specifications but that meet grade standards. Most dairy products for the Dairy Products Prices survey are not actually graded but meet the grade standards of authorities designated in the reporting specifications. For greater clarification the wording of the final rule has been changed to clarify that products that meet grade standards, as determined by the manufacturer, are to be reported.

19. *Exemptions*

One individual submitted comments proposing that mandatory reporting regulations not be “implemented except as they would apply to truly industrial level dairy production.” The commenter does not define a level of production to be considered as “truly industrial.” Stating concerns about compliance costs, the individual proposes that a cost-benefit analysis be performed for different levels of production for manufacturers before the regulation is implemented.

According to the cost-benefit analysis, the annual cost to manufacturers reporting product prices is estimated at \$381 per plant. Even for a small plant, such reporting costs would not be expected to be prohibitive. Concerning the maintaining of records, AMS has consulted with several reporting entities and has found that manufacturers already maintain records for at least 2 years as required by the final rule. With the interim final rule, AMS invited comments on whether all entities subject to the rule maintain the necessary records for at least 2 years. No such comments were received.

Under this final rule, manufacturers who process and market less than 1 million pounds of the applicable dairy products per year are exempt from price reporting requirements.

20. *Brokerage Fees and Clearing Charges*

Practically all firms that buy or sell products have marketing expenses. These marketing expenses are figured into the selling prices negotiated between buyers and sellers. These expenses often take the form of internal expenses, such as salaries paid to sales

people. They could also take the form of fees paid to third parties, such as brokerage fees, clearing charges, etc. To maintain consistency, none of the marketing expenses, whether internal expenses or fees paid to third parties, should be deducted from the prices reported to NASS. While the interim final rule excluded clearing charges from the reporting specifications for each product, this final rule specifies that in calculating the total dollars received or dollars per pound, the reporting entity shall not deduct brokerage fees or clearing charges paid by the manufacturer.

Effective Date

The availability of accurate market data for all market participants is extremely important. Buyers and seller of the basic dairy commodities, and indeed, the buyers and sellers of all dairy products depend on the accuracy of the prices affected by this final rule to provide them a sense of the current supply and demand conditions in the dairy sector. Improvements in the quality of price information of the basic dairy commodities—butter, cheddar, cheese, nonfat dry milk, and dry whey—were made by the interim final rule. This final rule makes certain amendments which further enhance the quality of such price information. For this reason, good cause is found that this rule will be effective the Sunday after publication in the **Federal Register**.

List of Subjects in 7 CFR Part 1170

Dairy products, Reporting and recordkeeping requirements, Cheese, Butter, Whey, Nonfat dry milk.

■ For the reasons set forth in the preamble, Title 7, subtitle B, chapter X is amended by revising part 1170, to read as follows:

PART 1170—DAIRY PRODUCT MANDATORY REPORTING

Sec.	
1170.1	Secretary.
1170.2	Act.
1170.3	Person.
1170.4	Dairy products.
1170.5	Manufacturer.
1170.6	Store.

Dairy Product Reporting Programs

1170.7	Reporting requirements.
1170.8	Price reporting specifications.
1170.9	Price reporting exemptions.
1170.10	Storage reporting specifications.
1170.11	Records.
1170.12	Confidential information.

Verification and Enforcement

1170.13	Verification of reports.
1170.14	Noncompliance procedures.

1170.15 Appeals.
1170.16 Enforcement.

Authority: 7 U.S.C. 1637–1637b, as amended by Pub. L. 106–532, 114 Stat. 2541 and Pub. L. 107–171, 116 Stat. 207.

§ 1170.1 Secretary.

Secretary means the Secretary of Agriculture of the United States or any other officer or employee of USDA to whom authority has been delegated.

§ 1170.2 Act.

Act means the Agricultural Marketing Act of 1946, 7 U.S.C. 1621 *et seq.*, as amended by the Dairy Market Enhancement Act of 2000, Public Law 106–532, 114 Stat. 2541, and the Farm Security and Rural Investment Act of 2002, Public Law 107–171, 116 Stat. 207.

§ 1170.3 Person.

Person means an individual, partnership, corporation, association, or any other business unit.

§ 1170.4 Dairy products.

Dairy Products means:

(a) Manufactured dairy products that are used by the Secretary to establish minimum prices for Class III and Class IV milk under a Federal milk marketing order issued under section 8c of the Agricultural Adjustment Act (7 U.S.C. 608c), reenacted with amendments by the Agricultural Marketing Agreement Act of 1937; and

(b) Substantially identical products designated by the Secretary in this Part.

§ 1170.5 Manufacturer.

Manufacturer means any person engaged in the business of buying milk in commerce for the purpose of manufacturing dairy products in one or more locations.

§ 1170.6 Store.

(a) *Store* means to place cheese or butter in a warehouse or facility which is artificially cooled to a temperature of 50 degrees Fahrenheit or lower and hold these dairy products for 30 days or more; or

(b) *Store* means to place nonfat dry milk or dry whey in a manufacturing plant, packaging plant, distribution point, or shipment in transit.

Dairy Product Reporting Programs

§ 1170.7 Reporting requirements.

(a) All dairy product manufacturers, with the exception of those who are exempt as described in § 1170.9, shall submit a report to National Agricultural Statistics Service (NASS) by noon on Wednesday of all products sold as specified in § 1170.8 during the seven days ending with the previous Saturday.

If a Federal holiday falls on a Tuesday or Wednesday, NASS will contact manufacturers via e-mail or phone concerning the applicable report deadline. The report is to be submitted on the appropriate forms supplied by NASS and shall indicate the name, address, plant location(s), quantities sold, total sales dollars or dollars per pound for the applicable products, and the moisture content where applicable. Each sale shall be reported for the time period when the transaction is completed, i.e. the product is “shipped out” and title transfer occurs. Each sale shall be reported either f.o.b. plant if the product is “shipped out” from the plant or f.o.b. storage facility location if the product is “shipped out” from a storage facility. In calculating the total dollars received or dollars per pound, the reporting entity shall neither add transportation charges incurred at the time the product is “shipped out” or after the product is “shipped out” nor deduct transportation charges incurred before the product is “shipped out.” In calculating the total dollars received or dollars per pound, the reporting entity shall not deduct brokerage fees or clearing charges paid by the manufacturer.

(b) Manufacturers or other persons storing dairy products are required to report, on a monthly basis, stocks of dairy products (as defined in § 1170.4) on hand, on the appropriate forms supplied by the NASS. The report shall indicate the name, address, and stocks on hand at the end of the month for each storage location.

§ 1170.8 Price reporting specifications.

The following are the reporting specifications for each dairy product:

(a) Specifications for Cheddar Cheese Prices:

- (1) Variety: Cheddar cheese.
- (2) Style: 40-pound blocks or 500-pound barrels.
- (3) Moisture Content:
 - (i) 40-pound blocks: Moisture content is not reported. Exclude cheese that will be aged.
 - (ii) 500-pound barrels: Report weighted average moisture content of cheese sold. NASS will adjust price to a benchmark of 38.0 percent based on standard moisture adjustment formulas. Exclude cheese with moisture content exceeding 37.7 percent.

- (4) Age: Not less than 4 days or more than 30 days on date of sale.
- (5) Grade:
 - (i) 40-pound blocks: Product meets Wisconsin State Brand or USDA Grade A or better standards.

(ii) 500-pound barrels: Product meets Wisconsin State Brand or USDA Extra Grade or better standards.

(6) Color:

(i) 40-pound blocks: colored and within the color range of 6–8 on the National Cheese Institute color chart.

(ii) 500-pound barrels: white.

(7) Packaging:

(i) 40-pound blocks: Price should reflect cheese wrapped in a sealed, airtight package in corrugated or solid fiberboard containers with a reinforcing inner liner or sleeve. Exclude all other packaging costs from the reported price.

(ii) 500-pound barrels: Exclude all packaging costs from the reported price.

(8) Exclude: Intra-company sales, resales of purchased cheese, forward pricing sales (sales in which the selling price was set [not adjusted] 30 or more days before the transaction was completed), cheese produced under faith-based close supervision and marketed at a higher price than the manufacturer’s wholesale market price for the basic commodity (for example, kosher cheese produced with a rabbi on site who is actively involved in supervision of the production process), sales under the Dairy Export Incentive Program or other premium-assisted sales (for example, export assistance sales through the Cooperatives Working Together program), and cheese certified as organic by a USDA-accredited certifying agent.

(b) Specifications for Butter Prices:

- (1) Variety: 80 percent butterfat, salted, fresh or storage.
- (2) Grade: Product meets USDA Grade AA standards.
- (3) Packaging: 25-kilogram and 68-pound box sales.

(4) Exclude: Unsalted and Grade A butter, intra-company sales, resales of purchased butter, forward pricing sales (sales in which the selling price was set [not adjusted] 30 or more days before the transaction was completed), butter produced under faith-based close supervision and marketed at a higher price than the manufacturer’s wholesale market price for the basic commodity (for example, kosher butter produced with a rabbi on site who is actively involved in supervision of the production process), sales under the Dairy Export Incentive Program or other premium-assisted sales (for example, export assistance sales through the CWT program), and butter certified as organic by a USDA-accredited certifying agent.

(c) Specifications for Dry Whey Prices:

- (1) Variety: Edible nonhygroscopic.
- (2) Age: No more than 180 days.
- (3) Grade: Product meets USDA Extra Grade standards.

(4) Packaging or container: 25-kilogram bag, 50-pound bag, tote, or tanker.

(5) Exclude: Sales of Grade A dry whey, intra-company sales, resales of purchased dry whey, forward pricing sales (sales in which the selling price was set [not adjusted] 30 or more days before the transaction was completed), dry whey produced under faith-based close supervision and marketed at a higher price than the manufacturer's wholesale market price for the basic commodity (for example, kosher dry whey produced with a rabbi on site who is actively involved in supervision of the production process), premium-assisted sales, and dry whey certified as organic by a USDA-accredited certifying agent.

(d) Specifications for the Nonfat Dry Milk Prices:

(1) Variety: Non-fortified.

(2) Age: No more than 180 days.

(3) Grade: Product meets USDA Extra Grade or USPH² Grade A standards.

(4) Packaging or container: 25-kilogram bag, 50-pound bag, tote, or tanker.

(5) Exclude: Nonfat dry milk manufactured using high heat process, sales of instant nonfat dry milk, sales of dry buttermilk products, intra-company sales, resales of purchased nonfat dry milk, forward pricing sales (sales in which the selling price was set [not adjusted] 30 or more days before the transaction was completed), nonfat dry milk produced under faith-based close supervision and marketed at a higher price than the manufacturer's wholesale market price for the basic commodity (for example, kosher nonfat dry milk produced with a rabbi on site who is actively involved in supervision of the production process), sales under the Dairy Export Incentive Program or other premium-assisted sales, and nonfat dry milk certified as organic by a USDA-accredited certifying agent.

§ 1170.9 Price reporting exemptions.

(a) Any manufacturer that processes and markets less than 1 million pounds of cheddar cheese per calendar year is exempt from reporting cheddar cheese sales as specified in § 1170.8(a).

(b) Any manufacturer that processes and markets less than 1 million pounds of butter per calendar year is exempt from reporting butter sales as specified in § 1170.8(b).

(c) Any manufacturer that processes and markets less than 1 million pounds of dry whey per calendar year is exempt

from reporting dry whey sales as specified in § 1170.8(c).

(d) Any manufacturer that processes and markets less than 1 million pounds of nonfat dry milk per calendar year is exempt from reporting nonfat dry milk sales as specified in § 1170.8(d).

§ 1170.10 Storage reporting specifications.

(a) Cold Storage Report:

(1) Reporting universe: All warehouses or facilities, artificially cooled to a temperature of 50 degrees Fahrenheit or lower, where dairy products generally are placed and held for 30 days or more. Excluded are stocks in refrigerated space maintained by wholesalers, jobbers, distributors, and chain stores; locker plants containing individual lockers; and frozen food processors whose inventories are turned over more than once a month.

(2) Products required to be reported:

(i) Natural cheese, domestic and foreign made, including barrel and cheese to be processed; American type cheeses, (cheddar, Monterey, Colby, etc.), including government owned stocks; Swiss; other natural cheese types (brick, mozzarella, Muenster, Parmesan, etc.). Exclude processed cheese.

(ii) Salted and unsalted butter, anhydrous milkfat (AMF), butter oil, including government owned stocks.

(b) Dairy Products Report:

(1) Reporting universe: All manufacturing plants.

(2) Products required to be reported:

(i) Nonfat dry milk.

(ii) Dry whey.

§ 1170.11 Records.

Each person required to report information to the Secretary shall maintain, and make available to the Secretary, on request, original contracts, agreements, receipts, and other records associated with the sale or storage of any dairy products during the 2-year period beginning on the date of the creation of the records.

§ 1170.12 Confidential information.

Except as otherwise directed by the Secretary or the Attorney General for enforcement purposes, no officer, employee, or agent of the United States shall make available to the public information, statistics, or documents obtained from or submitted by any person in compliance with the Dairy Product Mandatory Reporting program other than in a manner that ensures that confidentiality is preserved regarding the identity of person, including parties to a contract, and proprietary business information.

Verification and Enforcement

§ 1170.13 Verification of reports.

For the purpose of assuring compliance and verification, records and reports required to be filed by manufacturers or other persons pursuant to section 273(b)(1)(A)(i) of the Act, the Agricultural Marketing Service, through its duly authorized agents, shall have access to any premises where applicable records are maintained, where dairy products are produced or stored, and at any time during reasonable business hours shall be permitted to inspect such manufacturer or person, and any original contracts, agreements, receipts, and other records associated with the sale of any dairy products.

§ 1170.14 Noncompliance procedures.

(a) When the Secretary becomes aware that a manufacturer or person may have willfully delayed reporting of, or failed or refused to provide, accurate information pursuant to section 273(b)(1)(A)(i) of the Act, the Secretary may issue a cease and desist order.

(b) Prior to the issuance of a cease and desist order, the Secretary shall provide notice and an opportunity for an informal hearing regarding the matter to the manufacturer or person involved.

(c) The notice shall contain the following information:

(1) That the issuance of a cease and desist order is being considered;

(2) That the reasons for the proposed cease and desist order in terms sufficient to put the person on notice of the conduct or lack thereof upon which the notice is based;

(3) That within 30 days after receipt of the notice, the manufacturer or person may submit, in person, in writing, or through a representative, information and argument in opposition to the proposed cease and desist order; and

(4) That if no response to the notice is received within the 30 days after receipt of the notice, that a cease and desist order may be issued immediately.

(d) If a manufacturer or person requests a hearing, the hearing should be held at a location and time that is convenient to the parties concerned, if possible. The hearing will be held before the Deputy Administrator, Dairy Programs, Agricultural Marketing Service, or a designee. The manufacturer or person may be represented. Witnesses may be called by either party.

(e) The Deputy Administrator, Dairy Programs, Agricultural Marketing Service, or a designee will make a decision on the basis of all the

² USPH refers to the US Department of Health and Human Services—Public Health Service/Food and Drug Administration.

information in the administrative record, including any submission made by the manufacturer or person. The decision of whether a cease and desist order should be issued shall be made within 30 days after receipt of any information and argument submitted by the manufacturer or person. The cease and desist order shall be final unless the affected manufacturer or person requests a reconsideration of the order to the Administrator, Agricultural Marketing Service, within 30 days after the date of the issuance of the order.

§ 1170.15 Appeals.

If the cease and desist order is confirmed by the Administrator, Agricultural Marketing Service, the manufacturer or person may appeal the order in the appropriate United States District Court not later than 30 days after the date of the confirmation of the order.

§ 1170.16 Enforcement.

(a) If a person subject to the Dairy Product Mandatory Reporting program fails to obey a cease and desist order after the order has become final and unappealable, or after the appropriate United States district court has entered a final judgment in favor of the Administrator, Agricultural Marketing Service, the United States may apply to the appropriate United States district court for enforcement of the order.

(b) If the court determines that the cease and desist order was lawfully made and duly served and that the manufacturer or person violated the order, the court shall enforce the order.

(c) If the court finds that the manufacturer or person violated the cease and desist order, the manufacturer or person shall be subject to a civil penalty of not more than \$10,000 for each offense.

Dated: June 10, 2008.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E8-13550 Filed 6-16-08; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Paste

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 abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The supplemental ANADA adds effectiveness claims against various species of internal parasites when horses are treated with ivermectin paste.

DATES: This rule is effective June 17, 2008.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed a supplement to ANADA 200-326 for BIMECTIN (ivermectin) Paste 1.87% adding effectiveness claims against various species of internal parasites of horses. The supplemental ANADA is approved as of May 23, 2008, and 21 CFR 520.1192 is amended 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.

The agency has determined under 21 CFR 25.33(a)(1) 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 520

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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 360b.

■ 2. In § 520.1192, remove paragraphs (b)(4) and (e)(1)(ii)(C) and revise paragraph (b)(3) to read as follows:

§ 520.1192 Ivermectin paste.

* * * * *

(b) * * *

(3) Nos. 051311, 054925, and 061623 for use of a 1.87 percent paste for use as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section.

* * * * *

Dated: June 9, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8-13607 Filed 6-16-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Tylosin

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 Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA provides for revision of an effectiveness claim and pathogen nomenclature for a tylosin phosphate and sulfamethazine Type A medicated article used to manufacture medicated swine feeds.

DATES: This rule is effective June 17, 2008.

FOR FURTHER INFORMATION CONTACT: Timothy Schell, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8116, e-mail: timothy.schell@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 41-275 that provides for use of TYLAN 40 SULFA-G (tylosin phosphate and sulfamethazine) Elliptical Pellets, a Type A medicated article. The