

The sheller comment correctly pointed out several mistakes in the Minimum Quality Standards table following paragraph (a) in § 996.31. These errors were corrected in a document published in the **Federal Register** on September 11, 2003 (68 FR 53490).

#### Information Collection

The Act specifies in section 1604(c)(2)(A) that the standards established pursuant to the Act, may be implemented without regard to the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). Furthermore, this rule does not change the existing information collection burden.

After consideration of all relevant material presented, including the Board's recommendations, comments received, and other information, the interim final rule as published in the **Federal Register** on August 7, 2003 (68 FR 46919), together with the corrections published on September 11, 2003 (68 FR 53490) is finalized without change.

#### List of Subjects in 7 CFR Part 996

Food grades and standards, Imports, Peanuts, Reporting and recordkeeping requirements.

#### PART 996—MINIMUM QUALITY AND HANDLING STANDARDS FOR DOMESTIC AND IMPORTED PEANUTS MARKETING IN THE UNITED STATES

■ Accordingly, the interim final rule amending 7 CFR Part 996 which was published at 68 FR 46919 on August 7, 2003, and corrected at 68 FR 53490 on September 11, 2003, is adopted as a final rule without change.

Dated: June 2, 2004.

A.J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 04-12787 Filed 6-4-04; 8:45 am]

BILLING CODE 3410-02-P

#### DEPARTMENT OF AGRICULTURE

##### Agricultural Marketing Service

#### 7 CFR Part 1280

[No. LS-02-05]

#### Lamb Promotion, Research, and Information Program: Rules and Regulations

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Department of Agriculture (Department) is adopting, as

a final rule, without change, rules and regulations to implement the Lamb Promotion, Research, and Information Order (Order). The Order provides for the establishment of a national and industry-funded lamb promotion, research, and information program pursuant to the Commodity Promotion, Research, and Information Act of 1996 (Act). This final rule will implement Order provisions concerning the collection and remittance of assessments, procedures for obtaining a refund, reporting, and books and records.

**EFFECTIVE DATE:** July 7, 2004.

#### FOR FURTHER INFORMATION CONTACT:

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**SUPPLEMENTARY INFORMATION:** *Prior documents in this proceeding:* Invitation to submit proposals—November 23, 1999 (64 FR 65665) and January 12, 2000 (65 FR 1825); proposed Lamb Promotion, Research, and Information Order—September 21, 2001 (66 FR 48764); and final Lamb Promotion, Research, and Information Order—April 11, 2002 (67 FR 17848).

#### Executive Order 12866

The Office of Management and Budget (OMB) has waived the review process required by Executive Order (E.O.) 12866 for this action.

#### Executive Order 12988

This rule has been reviewed under E.O. 12988, Civil Justice Reform. This rule is not intended to have a retroactive effect. Section 524 of the Act provides that the Act shall not affect or preempt any other Federal or State law authorizing promotion or research relating to an agricultural commodity.

Under section 519 of the Act, a person subject to the Order may file a petition with the Department stating that the Order, any provision of the Order, or any obligation imposed in connection with the Order, is not established in accordance with the law, and request a modification of the Order or an exemption from the Order. Any petition filed challenging the Order, any provision of the Order, or any obligation imposed in connection with the Order, shall be filed within 2 years after the effective date of the Order, provision, or obligation subject to challenge in the petition. The petitioner will have the

opportunity for a hearing on the petition. Thereafter, the Department will issue a ruling on the petition. The Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of the entry of the Department's final ruling. Service of process in a proceeding may be made on the Department by delivering a copy of the complaint to the Department. If the court determines that the ruling is not in accordance with the law, the court shall remand the matter to the Department with direction to make such ruling as the court determining to be in accordance with the law or to take such further action as, in the opinion of the court the law requires. The pendency of a petition filed or an action commenced shall not operate as a stay of any action authorized by section 520 of the Act to be taken to enforce, including any rule, order, or penalty in effect.

#### Regulatory Flexibility Act and Paperwork Reduction Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), AMS has considered the economic effect of this final action on small entities. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened.

There are approximately 51,800 producers, 15,000 seedstock producers, 100 feeders, 571 first handlers, and 15 exporters of lamb who will be subject to the program. Most of the lamb producers, seedstock producers, feeders, and exporters would be classified as small businesses under the criteria established by the Small Business Administration (SBA) (13 CFR 121.201). Most first handlers would not be classified as small businesses. SBA defines small agricultural service firms as those whose annual receipts are less than \$5 million and small agricultural producers are defined as those having annual receipts of less than \$750,000. This number and size data remains the same as it appeared in the earlier analyses for the Order. Further, for purposes of this discussion and the prior Order analyses, there are approximately 3,318 market agencies, which include commission merchants, auction markets, brokers, or livestock markets in the business of receiving lambs for sale or commission. Most market agencies would be classified under SBA criteria as small businesses.

Also, under the program, there are approximately 20 national, State, or regional associations or organizations that are made up of and represent producers, feeders, seedstock producers, exporters, and first handlers.

The Act authorizes generic programs of promotion, research, and information for agricultural commodities. Congress found that it is in the national public interest and vital to the welfare of the agricultural economy of the United States to maintain and expand existing markets and develop new markets and uses for agricultural commodities through industry-funded, Government-supervised, generic commodity promotion, research, and information programs.

The Order will develop and finance an effective and coordinated program of promotion, research, and information to maintain and expand the markets for lamb and lamb products. For the purposes of this program, the term "lamb" as defined in the Order means, "any ovine animal of any age, including ewes and rams." A proposed Order was published in the **Federal Register** on September 21, 2001 (66 FR 48764). The comment period ended on November 20, 2001. The final Order was published in the **Federal Register** on April 11, 2002 (67 FR 17848). Collection of assessments began on July 1, 2002.

The April 11, 2002, publication included a regulatory flexibility analysis concerning the provisions of the final Order. That analysis took into account Order provisions concerning the collection and remittance of assessments, refunds, reports, and books and records. This rule will implement Order provisions concerning these requirements.

In this final rule, the section on assessments contains provisions on sharing proceeds of sale, market agencies, failure to collect, death, bankruptcy, receivership or incapacity to act, remittance of assessments, and non-producer status for certain transactions. The section on refunds includes provisions concerning the procedure for obtaining a refund and application form, submission of refund application to the Department, proof of payment of assessments, and payment of refunds. In addition, this final rule details provisions regarding reporting and maintenance of books and records and it establishes a reporting period.

With the exception of the form, Statement of Certification of Non-Producer Status (LS-78), the interim final rule and this final rule did not increase the burden on the industry from that previously imposed by the Order. The information collection

burden in connection with this form is minimal. The public reporting burden for this collection of information is estimated to average .03 hours per response for an estimate 3,318 respondents. The information collection requirements in the interim final rule were previously approved under OMB control number 0581-0203. That OMB control number has been merged into OMB control number 0581-0198.

#### Background

The Act (7 U.S.C. 7411-7425) authorizes the Department to establish generic programs of promotion, research, and information for agricultural commodities designed to strengthen an industry's position in the marketplace and to maintain and expand existing domestic and foreign markets and uses for agricultural commodities. Pursuant to the Act, a proposed Order was published in the **Federal Register** on September 21, 2001 (66 FR 48764). The final Order was published in the **Federal Register** on April 11, 2002 (67 FR 17848). Collection of assessments began on July 1, 2002. This program will be funded by assessments on domestic lamb producers, lamb feeders, exporters, and seedstock producers, in the amount of one-half cent (\$.005) per pound when live lambs are sold. For purposes of this program, the term "lamb" as defined in the Order means, "any ovine animal of any age, including ewes and rams."

First handlers, which means the packer or other person who buys or takes possession of lambs from a producer or feeder for slaughter, including custom slaughter, will be assessed an additional \$.30 cents per head purchased for slaughter or slaughtered by such first handler pursuant to a custom slaughter arrangement. Each person who processes or causes to be processed lamb or lamb products of that person's own production and markets the processed products will be assessed one-half cent (\$.005) per pound on the live weight at the time of slaughter and will be required to pay an additional assessment of \$.30 per head. Exporters who directly export lambs of their own production will be assessed in the amount of one-half cent (\$.005) per pound of live lambs exported. Assessment rates may be adjusted in accordance with applicable provisions of the Act and the Order.

The Order also requires persons to collect and remit assessments to the Lamb Promotion, Research, and Information Board (Board). Each producer, feeder, or seedstock producer is obligated to pay that portion of the

assessments that is equivalent to that producer's, feeder's, or seedstock producer's proportionate share and shall transfer the assessment to the subsequent purchaser, if applicable, and ultimately to the first handler or exporter who will remit the total assessments to the Board. Any person who processes or causes to be processed lamb or lamb products of the person's own production and markets the processed products will be required to pay an additional assessment and remit the total assessment to the Board. Each first handler who buys or takes possession of lambs from a producer or feeder for slaughter will be required to pay an additional assessment and remit the total assessment to the Board. Any person who exports live lambs will be required to collect and remit the total assessment to the Board at the time of export. Any exporter who directly exports lambs of their own production will pay an assessment to the Board. Additionally, a person who is a market agency; i.e., commission merchant, auction market, or broker in the business of receiving such lamb or lamb products for sale on commission for or on behalf of a producer, feeder, or seedstock producer, will be required to collect an assessment and shall transfer the collected assessment on to the subsequent purchaser(s). Ultimately, the first handler or exporter will remit the total assessment to the Board.

The Order imposes certain recordkeeping and reporting requirements on persons subject to the Order. First handlers and exporters will collect and remit the assessments on lamb and lamb products to the Board. Their responsibilities will include accurate recordkeeping and accounting of the number of lambs purchased, total weight in pounds, the names of the producers, seedstock producers, and feeders, the purchase date, the amount of assessments remitted, and the dates the assessments were paid. The required reporting forms require the minimum information necessary to effectively carry out the requirements of the program, and to fulfill the intent of the Act. Such records and reports shall be retained for at least 2 years beyond the fiscal year of their applicability. Presently, most of these requirements are likely being conducted as a normal business practice. There will be a minimal burden on persons who are market agencies. It is not anticipated that they will be required to submit records of their transactions involving lamb purchases and the required assessment collection to the Board. Information on such transactions can be

obtained through an audit of the market agencies' records. Such records are already being maintained as a normal business practice. This will include such records or documents that evidence payment of an assessment pursuant to the requirements in § 1280.225(b). In addition, market agencies must certify, as required by regulations prescribed by the Department, that the provisions of § 1280.217(b) have been met. This final rule includes these regulations.

#### Comments

On June 7, 2002, the Department published in the **Federal Register** (67 FR 39249) an interim final rule with request for comments. The comment period ended August 6, 2002.

The Department received 10 comments in a timely manner. In addition, five late comments were received. The late comments generally reflected the substance of comments timely received. Comments were received from producers, auction market operators, general farm and sheep organizations, and an association representing marketing agents. The changes suggested by the commenters are discussed below.

One commenter suggested that remitters should be allowed to remit the assessment and appropriate paperwork via the Internet. Currently, the Board does not have the ability to accept the transfer of funds or required forms via the Internet. The Board may choose to explore this option after an analysis of the current collection procedures. Accordingly, this suggestion is not adopted.

One commenter urged the Department to embark on an educational campaign aimed at the marketing agencies so there is a better understanding of what is required of them and to recommend procedures that can be used to meet those requirements. The Department agrees that a continuing educational program is warranted. Since the Board was seated in November 2002, Board representatives have attended annual meetings of several industry groups in order to better inform industry representatives about the program. Additionally, Board representatives have visited individual marketing agencies (*i.e.*, auction markets) to better educate them regarding their responsibilities for collecting the assessment, passing the assessment on to the subsequent buyer, and remitting the assessment to the Board. The Board has made these types of outreach activities a staple of their client communications program. Accordingly,

no change is needed as a result of this comment.

Some commenters recommended that the Department suspend the program until the Board is in place to allow sale and auction markets time to become fully educated and compliant with the Federal checkoff procedures. An extensive educational and outreach program was conducted beginning at least 2 years before the implementation of the program with the creation of the Exploration Team. In addition, in July 2002, the Department distributed informational packets to nearly 1,000 auction markets explaining the program. Further, the Board has been in place since November 2002. Accordingly, this suggestion is not adopted.

One commenter suggested that auction markets should not be required to complete a Non-Producer Status Form (LS-78). Auction markets generally facilitate the transaction between the seller and buyer and, usually, do not take ownership of the lambs. Under the Lamb Checkoff Program, auction markets are not required to complete the form unless they are seeking non-producer status. The Non-Producer Status form is intended for those market agents that are subject to § 1280.217 of the Order. Form LS-78 is intended to be completed only by those persons who buy and resell lambs within 10 days from the date of purchase on which the market agency acquired ownership. If an auction market buys animals in the company's name (taking title to the lambs) and resells them within 10 days from the date of purchase, they would be required to complete the form.

The Department received several comments regarding issues that were previously subject to public comment in connection with implementation of the Order and not part of the rules and regulations that are the subject of this rulemaking. The following comments were received: two commenters suggested that those persons who remit a small amount of assessment should be afforded the opportunity to remit the assessment when the amount reaches a certain dollar amount or be allowed to remit less often than required by the interim final rule; several commenters recommended assessing animals on a per head basis; one commenter suggested that ewes should be exempt from the assessment; several commenters suggested that the assessments should be collected and remitted at each transaction similar to other commodity checkoff programs; one commenter suggested that the Board should include one or two representatives from an association or

organization representing livestock markets that sell sheep; and one commenter suggested that auction markets remit the assessment directly to the Board.

On September 21, 2001, the proposed Order was published in the **Federal Register** with a request for public comment. The final Order was published and became effective on April 12, 2002. The interim final rule was published in the **Federal Register** on June 7, 2002, with a request for public comment. The comment period ended on August 6, 2002. The purpose of this final rule is to implement provisions of the Order provisions concerning the collection and remittance of assessments, procedures for obtaining a refund, reporting, and books and records. The aforementioned comments were not within the scope of this final rule and would require a change to the Order and further rulemaking. Accordingly, these suggestions are not adopted in this action.

Accordingly, after consideration of all comments, the interim final rule, as published in the **Federal Register** (67 FR 39249, June 7, 2002) is finalized without change.

#### List of Subjects in 7 CFR Part 1280

Administrative practice and procedure, Advertising, Consumer Information, Marketing agreements, Lamb and lamb products, Reporting and record keeping requirements.

#### PART 1280—LAMB PROMOTION, RESEARCH, AND INFORMATION

■ Accordingly, the interim final rule amending 7 CFR part 1280 which was published at 67 FR 39249 on June 7, 2002, is adopted as a final rule without change.

Dated: June 2, 2004

A.J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 04-12786 Filed 6-4-04; 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; Clindamycin Liquid

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.