risk based solely on the established nutritional risk status of another person, as provided in paragraphs (e)(1)(iv) and (e)(1)(v) of this section.

(ii) *Timing of nutritional risk data.*

(A) *Weight and height or length.* Weight and height or length shall be measured for program participation at the time of certification.

(B) *Hematological test for anemia.* For pregnant, breastfeeding, and postpartum women, and child applicants, the hematological test for anemia shall be performed or obtained from referral sources at the time of certification or within 90 days of the date of certification. However, a State agency cannot use hematological data obtained from referral sources that is taken more than 90 days prior to the date of certification for program participation.

Infants nine months of age and older (who have not already had a hematological test performed, between six and nine months of age, by a competent professional authority or obtained from referral sources), shall between nine and twelve months of age have a hematological test performed or obtained from referral sources. Such a test may be performed more than 90 days after the date of certification. For pregnant women, the hematological test for anemia shall be performed during their pregnancy. For persons certified as postpartum or breastfeeding women, the hematological test for anemia shall be performed after the termination of their pregnancy. The participant or parent/guardian shall be informed of the test results when there is a finding of anemia, and notations reflecting the outcome of the tests shall be made in the participant's file. Nutrition education, food package tailoring, and referral services shall be provided to the participant or parent/guardian, as necessary and appropriate.

(iii) *Breastfeeding dyads.* * * *

(iv) *Infants born to WIC mothers or women who were eligible to participate in WIC.* * * *

(v) *Presumptive eligibility for pregnant women.* A pregnant woman who meets the income eligibility standards may be considered presumptively eligible to participate in the program, and may be certified immediately without an evaluation of nutritional risk for a period up to 60 days. A nutritional risk evaluation of such woman shall be completed not later than 60 days after the woman is certified for participation. A hematological test for anemia is not required to be performed within the 60-day period unless the nutrition risk evaluation performed does not identify a risk factor. If no risk factor is identified, a hematological test for anemia must be performed or obtained from referral sources before the 60-day period elapses. Under the subsequent determination process, if the woman does not meet any nutritional risk criteria, including anemia criteria, the woman shall be determined ineligible and may not participate in the program for the reference pregnancy after the date of the determination, unless she subsequently reapplies for program benefits and is found to be both income eligible and at nutritional risk. Notification of the ineligibility determination shall be given in accordance with paragraph (j)(5) of this section. In addition, if the nutritional risk evaluation is not completed within the 60-day timeframe, the woman's participation shall end. As set forth in paragraph (j)(8) of this section, notification must be given prior to expiration of the certification period.

(vi) *Regression.* * * *

* * * * *

3. In § 246.14, paragraph (c)(2) is revised to read as follows:

§ 246.14 Program costs.

* * * * *

(c) * * *

(2) The cost of Program certification and nutrition assessment procedures, including the following:

(i) Laboratory fees incurred for up to two hematological tests for anemia per individual per certification period conducted to assess nutritional status and determine whether such individual is at nutritional risk. The first test shall be to determine anemia status. The second test may be performed only in follow up to a finding of anemia when deemed necessary for health monitoring as determined by the WIC State agency;

(ii) Expendable medical supplies necessary to assess nutritional status and to determine whether persons are at nutritional risk;

(iii) In connection with nutrition assessment and nutritional risk determinations, medical equipment used for taking anthropometric measurements, such as scales, measuring boards, and skin fold calipers; and for blood analysis to detect anemia, such as spectrophotometers, hematofluorometers and centrifuges; and

(iv) Salary and other costs for time spent on nutrition assessment and certification.

* * * * *

Dated: October 2, 1998.

Samuel Chambers, Jr.,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 98–30917 Filed 11–18–98; 8:45 am]

BILLING CODE 3410–30–U

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 956

[Docket Nos. 98AMA–FV–956–1; FV98–956–1]

Sweet Onions Grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon; Secretary's Decision and Referendum Order on Proposed Amendment of Marketing Agreement and Order No. 956

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule and referendum order.

SUMMARY: This decision proposes amendments to the marketing agreement and order (order) for sweet onions and provides Walla Walla Sweet Onion producers with the opportunity to vote in a referendum to determine if they favor the proposed amendments. The proposed amendments were submitted by the Walla Walla Sweet Onion Committee (committee), the agency responsible for local administration of the order. The proposed changes would broaden the scope of the order by adding authority for grade, size, quality, maturity, and pack regulations, mandatory inspection, marketing policy statements, and minimum quantity exemptions. In addition, a proposal is included to make a minor change in the committee's name. These changes are being proposed to improve the operation and functioning of the Walla Walla Sweet Onion marketing order program.

DATES: The referendum shall be conducted from November 25, 1998, through December 10, 1998. The representative period for the purpose of the referendum herein ordered is June 1, 1997, through May 31, 1998.

FOR FURTHER INFORMATION CONTACT: Robert Curry, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, Northwest Marketing Field Office, 1220 S.W. Third Avenue, room 369, Portland, Oregon 97204; telephone: (503) 326–2724, or Fax: (503) 326–7440; or Kathleen M. Finn, Marketing Specialist, Marketing Order Administration Branch, Fruit and

Vegetable Programs, AMS, USDA, room 2525–S, Washington, D.C. 20250–0200; telephone: (202) 720–2491, or Fax: (202) 205–6632. Small businesses may request information on compliance with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, P.O. Box 96456, room 2525–S, Washington, DC 20090–6456; telephone (202) 720–2491; Fax (202) 205–6632.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Notice of Hearing issued on March 25, 1998, and published in the April 1, 1998, issue of the **Federal Register** (63 FR 15787). Recommended Decision and Opportunity to File Written Exceptions issued on September 17, 1998, and published in the **Federal Register** on September 23, 1998 (63 FR 50802).

This administrative action is governed by the provisions of sections 556 and 557 of Title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Order 12866.

Preliminary Statement

The proposed amendments were formulated on the record of a public hearing held in Walla Walla, Washington, on April 7, 1998, to consider the proposed amendment of Marketing Agreement and Order No. 956, regulating the handling of sweet onions grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon, hereinafter referred to collectively as the ''order.'' The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*), hereinafter referred to as the Act, and the applicable rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders (7 CFR part 900). The Notice of Hearing contained amendment proposals submitted by the committee and the U.S. Department of Agriculture.

The committee's proposals would add the authority for grade, size, quality, maturity, and pack regulations, mandatory inspection, marketing policy statements, and minimum quantity exemptions. In addition, the committee proposed changing its name from the Walla Walla Sweet Onion Committee to the Walla Walla Sweet Onion Marketing Committee.

Also, the Fruit and Vegetable Programs of the Agricultural Marketing Service (AMS), U.S. Department of Agriculture, proposed to allow such changes as may be necessary to the order, if any or all of the above amendments are adopted, so that all of its provisions conform with the proposed amendment. No conforming changes have been deemed necessary.

Upon the basis of evidence introduced at the hearing and the record thereof, the Administrator of the Agricultural Marketing Service (AMS) on September 17, 1998, filed with the Hearing Clerk, U.S. Department of Agriculture, a Recommended Decision and Opportunity to File Written Exceptions thereto by October 23, 1998. None were received.

Small Business Considerations

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the AMS has considered the economic impact of this action on small entities. Accordingly, the AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions so that small businesses will not be unduly or disproportionately burdened. Small agricultural producers have been defined by the Small Business Administration (SBA) (13 CFR 121.601) as those having annual receipts of less than $500,000. Small agricultural service firms, which include handlers regulated under the order, are defined as those with annual receipts of less than $5,000,000.

Interested persons were invited to present evidence at the hearing on the probable regulatory and informational impact of the proposed amendments on small businesses. The record indicates that growers and handlers would not be unduly burdened by any additional regulatory requirements, including those pertaining to reporting and recordkeeping, that might result from this proceeding.

During the 1996–97 crop year, approximately 33 handlers were regulated under Marketing Order No. 956. In addition, there were about 64 producers of Walla Walla sweet onions in the production area. Marketing orders and amendments thereto are unique in that they are normally brought about through group action of essentially small entities for their own benefit. Thus, both the RFA and the Act are compatible with respect to small entities.

Twenty-four of the 33 handlers are also producers who handle their own onions. There are seven commercial packinghouses that pack approximately 90 percent of all Walla Walla sweet onions. In the 1996–97 season, the average f.o.b. price for Walla Walla sweet onions was $8.70 per 50-pound sack. Total production for the 1996–97 season was 666,000 50-pound containers. A handler who packed over 550,000 50-pound units would exceed the SBA definition of a small handler. According to record evidence, there are two dominant handlers in the industry and at least one of these handlers could be considered a large handler under this definition. The record revealed that all Walla Walla sweet onion growers would be considered small producers. Therefore, it can be concluded that the majority of growers and handlers would be considered small businesses.

The marketing order, promulgated in 1995, currently defines the production area where onions must be grown to be designated as Walla Walla sweet onions. It also provides the authority to fund research and promotion activities through assessments on handlers, as well as establish container regulations. Although the marketing order as currently written addresses some of the marketing problems facing the industry, the Walla Walla sweet onion industry continues to experience marketing problems.

Economic data presented on the record indicates that the acres planted have decreased from 1,800 in 1988 to 900 acres planted in 1997. This is a 50% decrease since 1988. Similarly, acres harvested have decreased from 1,600 in 1988 to 900 in 1997.

In addition, the data shows production has decreased dramatically from 1,280,000 50-pound containers in 1988 to 666,000 50-pound containers in 1997. This is a 48% decrease in production in the last 10 years.

Total crop values have declined from $9,345,000 in 1989 to $5,794,000 in 1997. This is a 38% decrease in total crop values in 9 years.

U.S. per capita consumption of fresh onions has increased from 10.7 pounds per year in 1981 to 17.5 pounds per year in 1997. This is a 64% increase in per capita use of fresh onions, while the production of Walla Walla sweet onions has decreased. This increased consumption shows that this industry has the potential to improve.

In addition, economic data shows that competition from other sweet onion producing areas has increased dramatically. Producers of Walla Walla sweet onions have lost market share to other sweet onions such as Georgia Vidalia onions, California Imperial onions, Hawaii Maui Sweets, New Mex. Sweets from New Mexico, and Texas hybrid 1015Y's.

The acres harvested and production of Vidalia onions have increased by 236% and 447%, respectively, since 1989. The Vidalia sweet onion industry's normal harvesting and shipping season begins in the middle of April and ends in late July. The Vidalia onion industry has

been successful in extending its shipping season into September and October by establishing controlled atmosphere storage capabilities. This may be having a price dampening effect on Walla Walla sweet onions because of the overlap of shipping seasons and direct competition caused by the extended season of Vidalia onions.

Of the six sweet onion-producing areas in the U.S., Walla Walla sweet onion prices are lower than Maui, Vidalia and Texas onions. In addition, the economic report presented on the record shows that Vidalia onions always receive higher prices than Walla Walla sweet onions with an average price differential of $5 per 50-pound container.

The Walla Walla sweet onion season begins in middle or late June and continues until the end of July. The shipping season lasts for approximately six weeks. Prices for Walla Walla sweet onions at the beginning of the season start relatively high. As the season progresses, prices generally fall. This seasonal price behavior has resulted in producers harvesting onions before they are fully matured. This has led to poor quality onions being sold on the market that make an unfavorable impression on consumers, supermarkets, and other outlets that handle Walla Walla sweet onions. In addition, this situation appears to have shortened the marketing season.

The quality at the beginning of the season has a tendency to set the market tone for the remainder of the season. If quality is high at the beginning of the season, this makes a favorable impression on buyers as well as consumers. With high quality onions at the start of the season, consumers are likely to become repeat customers. However, if quality is low at the beginning of the season, receivers as well as consumers are disappointed. Initial low quality will result in consumers shopping for alternative sweet onions and they will not be repeat purchasers.

Minimum quality and size requirements are established under marketing orders to ensure that substandard produce does not find its way to the market and destroy consumer confidence and harm producers' returns. The objective of implementing quality control and size provisions under marketing orders is to make the markets work more efficiently, improve quality, and to market preferred sizes. The use of quality and size standards through a grading scheme benefits consumers by assuring the buyers that they are getting high quality produce of desirable size. This helps build consumer demand in the long run. Minimum quality and size standards are deemed desirable because they prevent the shipment of poor quality produce, which ends up harming producers' ability to sell their product and consumers' willingness to buy.

The reputation of Walla Walla sweet onions has deteriorated over the recent years due to the poor quality of some of the onions marketed. Record evidence indicated that a surveillance project conducted during the 1997 harvest season by the Washington State Department of Agriculture on behalf of the committee noted that a significant amount of onions sold within the immediate Walla Walla area did not meet minimum U.S. standards. Walla Walla sweet onions usually meet at least U.S. No. 2 grade, but only a small volume meets U.S. No. 1 grade.

Establishing quality and size provisions under the Walla Walla sweet onion marketing order would provide an incentive for producers to allow their onions to fully mature, resulting in a higher quality of onion marketed. Establishing quality and size requirements would ensure consistent quality and acceptable sizes of onions throughout the season. This tends to benefit consumers through a higher quality of onion and benefits producers with a higher demand for their product. In the long run, high quality, seasonal produce builds name recognition and helps enhance demand.

The Walla Walla sweet onion industry has attempted to voluntarily implement quality control. Prior to implementation of the marketing order, the Walla Walla Sweet Onion Commission, a voluntary organization composed of producers and handlers, implemented quality rules for its members. These rules restricted the sale of U.S. No. 2 grade onions and culls from fresh market use, and included random inspections. Common defects that caused the onions to fail to meet these requirements were seed stems, immaturity, and decay. Because of the voluntary nature of these imposed regulations, this project was unsuccessful.

Currently, the marketing order allows only onions grown in the designated production area to be marketed as Walla Walla sweet onions. Research activities as well as promotional activities are also authorized under the current order. Broadening the scope of the order by authorizing minimum quality and size requirements would add another marketing tool to help the industry solve marketing problems, especially those related to quality. Minimum quality and size requirements would allow the industry to improve their name recognition with a quality product. Amending the order by authorizing the establishment of minimum quality and size requirements would help to expand markets and deliver a more consistent quality product of desirable size to the consumer.

Without any quality and size provisions in place, industry members can place substandard product on the market that is severely impacting the credibility and marketability of all Walla Walla sweet onions. Because of these current practices, the industry is experiencing problems establishing and maintaining markets in areas that have traditionally been strong. The industry has lost markets due to poor quality, short shelf life and increased competition from other sweet onion producing areas.

Minimum quality and size requirements would help alleviate some of these problems and work to improve producer returns by strengthening consumer and retail demand. Mandatory inspection requirements would make all producers and handlers responsible for the quality of the industry's output. Poor quality would not be mixed with better quality. The record revealed that most handlers are already sorting by size. The Department's Market News Service reports prices for jumbo and medium onions, which further indicates that handlers are sorting by size. Most handlers also pack to a certain quality standards, usually based on U.S. grade standards. Therefore, handlers would not be required to drastically modify their packing operations or purchase new equipment. The committee considered grower and handler costs very seriously and even discussed the cost burden between larger and smaller handlers. The minimum quantity exemption should address such concerns.

Growers may be faced with a potential cost item related to improved equipment that could be needed in order to meet minimum quality or size standards. A handler testified that growers could update their mechanical seeders so that the seeds could be planted equidistant from each other, which would result in onions with better shape, more uniformity and larger size. There are increasingly more growers that are purchasing this equipment or contracting with other growers that have the seeders. Seed coating or pelleting is another alternative for better seed placement, which is less expensive than the purchase of a highly advanced seeder. The seed coating adds a clay-like

material to the exterior of the seed, so that the seeders do not cause two or three seeds to drop at the same time. It appears that costs associated with growers modifying their cultural practices to abide by minimum quality and size standards would be minimal and offset by improved producer returns.

A witness for the committee testified that the benefits of including the authority for minimum quality and size standards would far outweigh any negative impact to producers and handlers and the industry could start rebuilding markets and creating new ones.

The Federal-State Inspection Service Office that is responsible for inspecting Walla Walla sweet onions is currently located in Pasco, Washington, less than 50 miles from Walla Walla. According to record testimony, inspectors would be staffed in Walla Walla during the season if mandatory inspection was implemented.

Inspection costs in the State of Washington are computed on an hourly basis or a per unit basis, whichever is greater. If the hourly rate is used, the rate applies to the total number of the inspector's hours, including travel time. Depending upon the workload, inspectors could be based in Walla Walla during the season, which would lessen travel costs. Record testimony indicated that the hourly inspection rate is $26, with a two-hour minimum, or $52, for inspection or $208 for an eight-hour day. However, the State of Washington Agriculture Code regulations appearing at Chapter 16–400–210 WAC provide that the hourly inspection rate is $23, with no minimum time required. In accordance with the Rules of Practice and Procedure governing the formulation of marketing agreements and orders (7 CFR Part 900), official notice has been taken of the fees set forth in the State of Washington regulations at Chapter 16–400–210 WAC. The fee schedule will be used in our analysis. On a per unit basis, the inspection fee is $.04 per 50-pound unit.

As stated above, inspection costs are computed on an hourly basis or a per unit basis, whichever is greater. For example, if an inspection was requested on 100 50-pound containers and the inspection lasted one hour, the per unit cost for inspecting the lot would be $4, and the per hour cost would be $23. Under this scenario, the handler would be charged $23 for the inspection, the greater amount. This would average $.23 per unit.

Under the current fee schedule, it would be necessary for the inspection office to inspect over 4,600 50-pound units of onions per day in order to maintain the fee at $.04 per 50-pound unit. If handlers do not handle over 4,600 50-pound units per day, their inspection costs would be computed at the hourly rate. Even for handlers who normally handle that volume, there would be times during the season, particularly in the beginning and end of the season, where the volume of onions inspected would not be at a level where the $.04 per 50-pound unit could be used. The fees would convert to the hourly rate.

Record testimony indicated that the committee is concerned with increased costs associated with these proposals, particularly, the costs of inspection. The committee discussed options to address these concerns and developed two remedies intended to alleviate the cost burdens on small handlers. First, the committee recommended adding authority in the order for the committee to contract with the Federal-State Inspection Service and pay for all inspections of Walla Walla sweet onions. Second, the committee recommended an exemption from inspection for handlers of small lots of onions.

Under the scenario of contracting with the inspection service, each handler would pay a separate assessment for inspection costs at a per unit price. All handlers would pay the same price per bag for inspection, whether exempt or not. Under such a contract, the larger volume handlers would pay more of the inspection costs because they handle so many more units of onions. In this manner, the burden of inspection costs for smaller volume handlers could be minimized. This was discussed with representatives of the inspection service.

A Washington State inspector confirmed that travel costs would be lessened if an inspector was based in Walla Walla. However, the inspector indicated that $.04 per 50-pound unit would be the minimum cost for the inspection. Costs could increase depending on the workload. If the workload was light, such as late in the season when the quantities of onions are diminishing, it could be more costly for an inspector to conduct inspections on smaller lots. It could be necessary to convert the cost to an hourly cost, which would exceed $.04 per 50-pound unit.

There have been discussions regarding contractual relationships with the inspection service but factors such as inspection of small quantities would need to be addressed in the contract. The inspector testified that the inspection office must cover the cost of inspectors and if there was not a full day's work in Walla Walla, the inspector would need to travel elsewhere. These situations would need to be factored into any contractual agreements. A witness for the proposals testified that because of the variables associated with inspecting Walla Walla sweet onions, it is estimated the cost of inspection would range between $.04 and $.06 per 50-pound unit if the per unit price were used in a contractual agreement. The committee could consider only contracting with the inspection service during the busiest parts of the season in order to keep the inspection cost lower. The committee could also consider only regulating for part of the season.

Another option the committee developed to address the issues of costs on small handlers would provide an exemption for handlers who handle up to, but not more than 2,000 pounds of Walla Walla sweet onions per shipment. These handlers would be exempt from inspection requirements, but these exempt onions would still be required to meet the quality and size requirements in effect at the time of shipment. Handlers could make more than one exempt shipment per day as long as each shipment was at or below the 2,000-pound exemption. These exempt onions would not be exempt from assessments. The committee would be able to recommend modification of the minimum quantity exemption through informal rulemaking, if necessary. The committee would be responsible for monitoring compliance with this proposal. If necessary, the committee would conduct spot inspections at the committee's expense to ensure that inspection-exempt onions were meeting the established quality and size regulations.

Record testimony indicated the implementation of these proposals could necessitate that the committee increase the manager's work hours in order to monitor compliance with these provisions. This could result in the need to recommend an increase in the marketing order assessment rate. However, an increase is not expected because the increased production, demand, and expanded markets would help to supply ample funds to administer the program without increasing the assessment rate.

When the committee was considering amending the marketing order to include quality and size requirements, a compliance subcommittee was appointed to address concerns of small producers and handlers. The subcommittee is composed of producers and handlers who developed the

minimum quantity exemption provisions of the committee's proposals. The subcommittee considered different options during their deliberations and determined that the current proposed amendments were the most advantageous to small growers and handlers while still allowing quality objectives to be met.

Inspection requirements would not apply to shipments of Walla Walla sweet onions that are 2,000 pounds or less. However, these onions would be required to meet any minimum requirements in effect at the time of shipment. This would be enforced through periodic spot examinations conducted by the committee. A general consensus among industry members was that establishing a minimum quantity exemption was necessary to relieve any undue financial burden on small volume handlers. The committee would be responsible for monitoring compliance with this proposal by conducting spot inspections, if necessary, at the committee's expense. It is estimated that compliance with these proposals could increase administrative costs for the committee by $3,000, or a 3 percent increase in the current committee budget.

As previously stated, 7 commercial handlers pack 90 percent of the industry's crop. Approximately 26 handlers handle the remaining 10 percent. With the 2,000 pound inspection exemption implemented, it is estimated that 50 percent of the remaining 26 handlers would be exempt from mandatory inspection. This represents approximately 42 acres or 25,000 50-lb. units, which is 5 percent of the crop. Therefore, it appears that at least 13 handlers would be exempt from inspection, while 95 percent of the production would still be inspected. This proposed amendment would minimize the impact on small handlers without jeopardizing quality objectives.

These exempt onions would not be exempt from assessments. In addition, exempt onions would still be required to meet the minimum quality and size requirements established by the committee and approved by the Secretary. Committee staff would conduct spot inspections to monitor the exempt handlers' activities. The proposal allows for modification of this provision depending on industry needs. The committee does not believe it would ever recommend not having a minimum quantity exemption.

A witness for the proposals testified that the only cost increase would be the cost of inspection. He further stated that the cost of inspection is a minor cost item, compared to labor and growing costs. Walla Walla sweet onion production is labor-intensive and high cost. A premium price is necessary for the onions to pay the costs of production.

This witness testified that a grower normally has $1,800 to $2,000 an acre invested in production prior to harvest. Using this estimate and assuming a yield of 190 50-pound units per acre, inspection costs (estimated at $.04 to $.06 per 50-pound unit) are estimated to be $7.60 to $11.40 per acre, or an estimated 0.4 to 0.6 percent increase of pre-harvest cost.

Following is an example of possible costs associated with implementing quality and size standards. Testimony revealed that if a U.S. Commercial grade were established as a minimum quality standard, 5 to 10 percent of the onions would not meet that grade and would have to be disposed of in secondary outlets. Using last year's production figures (1996–97), 666,000 50-pound containers were produced for sale. If 10 percent would not make U.S. Commercial grade, 66,600 50-pound containers would need to be disposed of in secondary outlets. It is estimated that 5 percent of the crop, or 33,300 pounds, would be exempt from inspection. Therefore, approximately 566,100 50-pound containers would need to be inspected. Using the high inspection cost estimate of $.06 per container, inspection costs for the entire crop would be $33,966. Seven commercial packing houses pack 90 percent of the crop which would account for $30,569.40 of the costs. The remaining 26 small handlers would be responsible for the remaining inspection costs of $3,396.60, or approximately $131 per handler for inspection fees for that season.

Minimum quality and size standards would maintain the integrity of the product so that the commodities' overall quality image is not diminished by a low quality sample. The principle objective of a grading system is to make the market work more efficiently. Minimum quality and size requirements would improve information between buyers and sellers. Contracts could be made based on grade specifications, and buyers need not personally inspect each lot of product. Standardization of quality and size reduces uncertainty between buyers and sellers, and this helps reduce marketing costs. The goal of an effective grading system is to improve quality and size. Minimum quality and size standards would help ensure that substandard produce does not find its way to the market and destroy consumer confidence and harm producers' returns.

The ability of producers of Walla Walla sweet onions to increase the demand for their product depends on their ability to differentiate their product and to create a favorable image (including quality) with consumers. In recent years, this favorable image has deteriorated. Culling out low quality produce of undesirable size, even though the demand for it may be elastic, may increase total returns. The price increase from the higher quality sold is expected to be large enough to offset the effect of the reduced quantity sold, even after the costs of culling are covered.

Record evidence also shows that the collection of information under the marketing order would not be effected if the amendments were made to the marketing order. No increase in information collection would occur with the adoption of the amendments alone. However, if these proposals are implemented and the committee recommends regulations to impose quality and size requirements, it is possible that additional information would be needed from handlers to aid in administering the program effectively. It is also possible that because inspection certificates would be received by the committee, needed information could be collected from the certificates and the information collection requirements could be reduced. Whatever information collection changes result from any regulations, the committee and the Department would submit such changes to the Office of Management and Budget (OMB) for approval. Current information collection requirements for Part 956 are approved by OMB under OMB number 0581–0172.

The proposed amendment to modify the name of the committee from the Walla Walla Sweet Onion Committee to the Walla Walla Sweet Onion Marketing Committee would have no regulatory impact on handlers or growers.

Accordingly, this action would not impose any additional reporting or recordkeeping requirements on either small or large Walla Walla sweet onion handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

The Department has not identified any relevant Federal rules that duplicate, overlap or conflict with this proposed rule. All of these amendments are designed to enhance the administration and functioning of the marketing order to the benefit of the industry.

While the implementation of quality and size requirements may impose some additional costs on handlers, the costs are minimal and uniform on all handlers. Some of these costs may be passed on to growers. However, these costs would be offset by the benefits derived by the operation of the marketing order. In addition, the meetings regarding these proposals as well as the hearing date were widely publicized throughout the Walla Walla sweet onion production area industry and all interested persons were invited to attend the meetings and the hearing and participate in committee deliberations on all issues. All committee meetings and the hearing were public forums and all entities, both large and small, were able to express views on these issues. Finally, interested persons were invited to submit information on the regulatory and informational impacts of this action on small businesses.

Civil Justice Reform

The amendments proposed herein have been reviewed under Executive Order 12988, Civil Justice Reform. They are not intended to have retroactive effect. If adopted, the proposed amendments would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with the amendments.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided an action is filed not later than 20 days after date of the entry of the ruling.

Findings and Conclusions

The material issues, findings and conclusions, rulings, and general findings and determinations included in the Recommended Decision set forth in the September 23, 1998, issue of the **Federal Register** (63 FR 50802) are hereby approved and adopted.

Marketing Agreement and Order

Annexed hereto and made a part hereof is the document entitled ''Order Amending the Order Regulating the Handling of Sweet Onions Grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon.'' This document has been decided upon as the detailed and appropriate means of effectuating the foregoing findings and conclusions.

It is hereby ordered, That this entire decision be published in the **Federal Register**.

Referendum Order

It is hereby directed that a referendum be conducted in accordance with the procedure for the conduct of referenda (7 CFR part 900.400 *et seq.*) to determine whether the issuance of the annexed order amending the order regulating the handling of sweet onions grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon, is approved or favored by producers, as defined under the terms of the order, who during the representative period were engaged in the production of sweet onions grown in the production area.

The representative period for the conduct of such referendum is hereby determined to be June 1, 1997, through May 31, 1998.

The agents of the Secretary to conduct such referendum are hereby designated to be Robert Curry, Marketing Specialist, and Gary Olson, Regional Manager, Northwest Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, 1220 S.W. Third Avenue, room 369, Portland, Oregon 97204; telephone (503) 326–2724.

List of Subjects in 7 CFR Part 956

Marketing agreements, Onions, Reporting and recordkeeping requirements.

Dated: November 13, 1998.

Enrique E. Figueroa,

Administrator, Agricultural Marketing Service.

Order Amending the Order Regulating the Handling of Sweet Onions Grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon [1]

Findings and Determinations

The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the order; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) *Findings and Determinations Upon the Basis of the Hearing Record.*

Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*), and the applicable rules of practice and procedure effective thereunder (7 CFR part 900), a public hearing was held upon the proposed amendments to the Marketing Agreement and Order No. 956 (7 CFR part 956), regulating the handling of sweet onions grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon.

Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The marketing agreement and order, as hereby proposed to be amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(2) The marketing agreement and order, as hereby proposed to be amended, regulate the handling of sweet onions grown in the production area in the same manner as, and is applicable only to persons in the respective classes of commercial and industrial activity specified in the marketing order upon which hearings have been held;

(3) The marketing agreement and order, as hereby proposed to be amended, are limited in application to the smallest regional production area which is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the Act; and

(4) The marketing agreement and order, as hereby proposed to be amended, prescribe, insofar as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of sweet onions grown in the production area; and

(5) All handling of sweet onions grown in the production area is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

[1] This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

Order Relative to Handling

It is therefore ordered, That on and after the effective date hereof, all handling of sweet onions grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon, shall be in conformity to, and in compliance with, the terms and conditions of the said order as hereby proposed to be amended as follows:

With one exception, the provisions of the proposed marketing agreement and the order amending the order contained in the Recommended Decision issued by the Administrator on September 17, 1998, and published in the **Federal Register** on September 23, 1998, shall be and are the terms and provisions of this order amending the order and are set forth in full herein. One change is made herein for clarity in § 956.70(a).

PART 956—SWEET ONIONS GROWN IN THE WALLA WALLA VALLEY OF SOUTHEAST WASHINGTON AND NORTHEAST OREGON

1. The authority citation for 7 CFR part 956 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. In part 956, § 956.14 is added and reserved, and new §§ 956.15 and 956.16 are added to read as follows:

§ 956.15 Grade and size.

Grade means any of the officially established grades of onions, including maturity requirements and *size* means any of the officially established sizes of onions as set forth in the United States standards for grades of onions or amendments thereto, or modifications thereof, or variations based thereon, or States of Washington or Oregon standards of onions or amendments thereto or modifications thereof or variations based thereon, recommended by the committee and approved by the Secretary.

§ 956.16 Pack.

Pack means a quantity of Walla Walla Sweet Onions specified by grade, size, weight, or count, or by type or condition of container, or any combination of these recommended by the committee and approved by the Secretary.

§ 956.20 [Amended]

3. In § 956.20, paragraph (a) is amended by adding the word ''Marketing'' immediately following the word ''Onion'' in the first sentence.

4. In part 956, a new § 956.60 is added to read as follows:

§ 956.60 Marketing policy.

(a) *Preparation.* Prior to each marketing season, the committee shall consider and prepare a proposed policy for the marketing of Walla Walla Sweet Onions. In developing its marketing policy, the committee shall investigate relevant supply and demand conditions for Walla Walla Sweet Onions. In such investigations, the committee shall give appropriate consideration to the following:

(1) Market prices for sweet onions, including prices by variety, grade, size, quality, and maturity, and by different packs;

(2) Supply of sweet onions by grade, size, quality, maturity, and variety in the production area and in other sweet onion producing sections;

(3) The trend and level of consumer income;

(4) Establishing and maintaining orderly marketing conditions for Walla Walla Sweet Onions;

(5) Orderly marketing of Walla Walla Sweet Onions as will be in the public interest; and

(6) Other relevant factors.

(b) *Reports.* (1) The committee shall submit a report to the Secretary setting forth the aforesaid marketing policy, and the committee shall notify producers and handlers of the contents of such report.

(2) In the event it becomes advisable to shift from such marketing policy because of changed supply and demand conditions, the committee shall prepare an amended or revised marketing policy in accordance with the manner previously outlined. The committee shall submit a report thereon to the Secretary and notify producers and handlers of the contents of such report on the revised or amended marketing policy.

5. Section 956.62 is revised to read as follows:

§ 956.62 Issuance of regulations.

(a) Except as otherwise provided in this part, the Secretary shall limit the shipment of Walla Walla Sweet Onions by any one or more of the methods hereinafter set forth whenever the Secretary finds from the recommendations and information submitted by the committee, or from other available information, that such regulation would tend to effectuate the declared policy of the Act. Such limitation may:

(1) Regulate in any or all portions of the production area, the handling of particular grades, sizes, qualities, or maturities of any or all varieties of Walla Walla Sweet Onions, or combinations thereof, during any period or periods;

(2) Regulate the handling of particular grades, sizes, qualities, or maturities of Walla Walla Sweet Onions differently, for different varieties or packs, or for any combination of the foregoing, during any period or periods;

(3) Provide a method, through rules and regulations issued pursuant to this part, for fixing the size, capacity, weight, dimensions, markings or pack of the container or containers, which may be used in the packaging or handling of Walla Walla Sweet Onions, including appropriate logo or other container markings to identify the contents thereof;

(4) Regulate the handling of Walla Walla Sweet Onions by establishing, in terms of grades, sizes, or both, minimum standards of quality and maturity.

(b) The Secretary may amend any regulation issued under this part whenever the Secretary finds that such amendment would tend to effectuate the declared policy of the Act. The Secretary may also terminate or suspend any regulation or amendment thereof whenever the Secretary finds that such regulation or amendment obstructs or no longer tends to effectuate the declared policy of the Act.

6. Section 956.64 is revised to read as follows:

§ 956.64 Minimum quantities.

During any period in which shipments of Walla Walla Sweet Onions are regulated pursuant to this part, each handler may handle up to, but not to exceed, 2,000 pounds of Walla Walla Sweet Onions per shipment without regard to the inspection requirements of this part: *Provided*, That such Walla Walla Sweet Onion shipments meet the minimum requirements in effect at the time of the shipment pursuant to § 956.62. The committee, with the approval of the Secretary, may recommend modifications to this section and the establishment of such other minimum quantities below which Walla Walla Sweet Onion shipments will be free from the requirements in, or pursuant to, §§ 956.42, 956.62, 956.63, and 956.70, or any combination thereof.

7. In part 956, a new center heading and § 956.70 are added to read as follows:

Inspection

§ 956.70 Inspection and certification.

(a) During any period in which shipments of Walla Walla Sweet Onions are regulated pursuant to this subpart, no handler shall handle Walla Walla Sweet Onions unless such onions are inspected by an authorized representative of the Federal-State Inspection Service, or such other inspection service as the Secretary shall designate and are covered by a valid

inspection certificate, except when relieved from such requirements pursuant to §§ 956.63 or 956.64, or both. Upon recommendation of the committee, with approval of the Secretary, inspection providers and certification requirements may be modified to facilitate the handling of Walla Walla Sweet Onions.

(b) Regrading, resorting, or repacking any lot of Walla Walla Sweet Onions shall invalidate prior inspection certificates insofar as the requirements of this section are concerned. No handler shall ship Walla Walla Sweet Onions after they have been regraded, resorted, repacked, or in any other way further prepared for market, unless such onions are inspected by an authorized representative of the Federal-State Inspection Service, or such other inspection service as the Secretary shall designate: *Provided,* That such inspection requirements on regraded, resorted, or repacked Walla Walla Sweet Onions may be modified, suspended, or terminated under rules and regulations recommended by the committee, and approved by the Secretary.

(c) Upon recommendation of the committee, and approval of the Secretary, all Walla Walla Sweet Onions that are required to be inspected and certified in accordance with this section shall be identified by appropriate seals, stamps, tags, or other identification to be furnished by the committee and affixed to the containers by the handler under the direction and supervision of the Federal-State or Federal inspector, or the committee. Master containers may bear the identification instead of the individual containers within said master container.

(d) Insofar as the requirements of this section are concerned, the length of time for which an inspection certificate is valid may be established by the committee with the approval of the Secretary.

(e) When Walla Walla Sweet Onions are inspected in accordance with the requirements of this section, a copy of each inspection certificate issued shall be made available to the committee by the inspection service.

(f) The committee may enter into an agreement with an inspection service with respect to the costs of the inspection as provided by paragraph (a) of this section, and may collect from handlers their respective pro rata shares of such costs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 320

[Docket No. 98N–0778]

Bioavailability and Bioequivalence Requirements; Abbreviated Applications; Proposed Revisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise its regulations on bioavailability and bioequivalence and on the content and format of an abbreviated application to reflect current FDA policy and to correct certain typographical and inadvertent errors. This action is intended to improve the accuracy and clarity of the regulations.

DATES: Written comments by February 2, 1999. FDA proposes that any final rule based on this proposal become effective 60 days after its date of publication in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA regulations require persons submitting a new drug application (NDA) to provide bioavailability information (21 CFR 314.50(c)(2)(vi) and (d)(3)), and persons submitting an abbreviated new drug application (ANDA) or abbreviated antibiotic application (AADA) to provide information pertaining to bioavailability and bioequivalence (§ 314.94(a)(7) and (d)(3) (21 CFR 314.94(a)(7) and (d)(3))).

FDA regulations in part 320 (21 CFR part 320) establish definitions and requirements for bioavailability and bioequivalence studies. FDA finalized the bioavailability and bioequivalence regulations on January 7, 1977 (42 FR 1624), and amended these regulations on April 28, 1992 (57 FR 17950). The 1992 amendments were designed to reflect statutory changes resulting from the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417).

Bioavailability, in general, refers to the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action (§ 320.1(a)). Bioequivalence, in general, refers to the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate (e.g., in certain controlled release dosage forms), certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action (§ 320.1(e)).

II. Description of the Proposed Rule

The proposed rule would revise FDA regulations pertaining to abbreviated applications, bioavailability, and bioequivalence to reflect current agency policy, to correct typographical and inadvertent errors, and to clarify existing provisions. The proposed amendments follow.

Section 314.94(a)(9) establishes information requirements for the chemistry, manufacturing, and controls section of an abbreviated application. Section 314.94(a)(9) provides that an abbreviated application may have different inactive ingredients than the reference listed drug as long as the applicant identifies and characterizes the inactive ingredients in the proposed drug product and provides information demonstrating that the inactive ingredients do not affect the safety of the drug product. The proposed rule would amend this section to recognize the possibility that the use of different inactive ingredients may also affect a product's efficacy.

Section 314.94(a)(9)(v) establishes the requirements for inactive ingredient changes permitted in drug products intended for topical use. The proposed rule would revise this section to include solutions for aerosolization or nebulization as well as nasal solutions. This change is intended to clarify that these solutions may be characterized as drug products intended for topical use.