Order to provide authority for Customs to collect the assessment on all imported, flavored honey.

A proposed rule was published in the Federal Register on March 27, 1996, [60 FR 13463]. No comments were received on the proposal.

This rule adds the new 2106.90.9988 HTS code for flavored honey to section 1240.115(e) of the rules and regulations issued under the Order. Flavored honey would be assessed at the one-cent-per-pound rate. A conversion factor is not necessary because the amount of honey in flavored honey is estimated at 99 percent of the total product. Customs will notify importers 60 to 90 days before it begins collecting the assessment on flavored honey.

Pursuant to the provisions in 5 U.S.C. 553, it is found and determined that good cause exists for not postponing the effective date of this action until 30 days after publication in the Federal Register because: (1) This action puts into effect an HTS Code for flavored honey for the U.S. Customs Service to use in assessing imported flavored honey; (2) flavored honey is currently being imported; (3) a 30-day comment period was provided and no comments were received; and (4) no useful purpose would be served by a delay of the effective date.

After consideration of all relevant material presented, it is found that this regulation, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 1240

Advertising, Agricultural research, Honey, Imports, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR Part 1240 is amended as follows:

PART 1240—HONEY RESEARCH, PROMOTION, AND CONSUMER INFORMATION ORDER

1. The authority citation for 7 CFR Part 1240 continues to read as follows:

Authority: 7 U.S.C. 4601–4612.

2. In § 1240.115, paragraph (e) is revised to read as follows:

§ 1240.115 Levy of assessments.

* * * * *

(e) The U.S. Customs Service (USCS) will collect assessments on all honey or honey products where honey is the principal ingredient imported under its tariff schedule (HTS heading numbers 0409.00.00 and 21006.90.9988) at the time of entry or withdrawal for consumption and forward such assessment as per the agreement between the USCS and USDA. Any importer or agent who is exempt from payment of assessments pursuant to § 1240.42 (a) and (b) of the Order may apply to the Board for reimbursement of such assessment paid.

* * * * *

Dated: June 3, 1996.

Robert C. Keeney,

Director, Fruit and Vegetable Division.

[FR Doc. 96–14758 Filed 6–10–96; 8:45 am]

BILLING CODE 3410–02–P

Animal and Plant Health Inspection Service

9 CFR Parts 101 and 112

[Docket No. 93–167–2]

Viruses, Serums, and Toxins and Analogous Products; Master Labels

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the packaging and labeling of veterinary biologicals to implement the use of a master label. The use of a master label system will reduce the number of copies of labels that are required to be submitted for review and approval, and allow labels with certain minor revisions to be used sooner than would be possible under the current regulations. A definition of ''master label'' is added to the regulations. In the final rule, the provision for the use of labels with certain minor changes prior to APHIS approval is extended to include previously approved lebels.

The amendments are necessary in order to improve label approval procedures by establishing a master label system. The effect of the amendment will be to streamline the procedure for requesting and receiving approval to use new or revised labels for veterinary biologicals.

EFFECTIVE DATE: July 11, 1996.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, APHIS, BBEP, 4700 River Road, Unit 148, Riverdale, MD 20737–1237, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 112 pertain to the packaging and labeling of veterinary biologicals. The regulations require that all labels for veterinary biologicals be submitted and reviewed for compliance with the regulations and approved in writing prior to use. The Animal and Plant Health Inspection Service (APHIS) has issued licenses under the Virus-Serum-Toxin Act (21 U.S.C. 151–159) for some 2300 veterinary biological products. Each licensed biological product is required to have approved packaging and labeling applicable to a variety of container sizes, trade names, producers, subsidiaries, and distributors.

On March 17, 1995, we published in the Federal Register (60 FR 14392–14395, Docket No. 93–167–1) a proposal to amend the regulations regarding the packaging and labeling of veterinary biologicals to implement the use of a master label system. The use of a master label system would reduce the number of copies of labels that are required to be submitted for review and approval, and would allow labels with certain minor revisions to be used sooner than would be possible under the current regulations. A definition of ''master label'' would be added to the regulations. The amendments are necessary in order to improve label approval procedures by establishing a master label system. The effect of the amendment would be to steamline the procedure for requesting and receiving approval to use new or revised labels for veterinary biologicals.

We solicited comments concerning our proposal for 60 days ending May 16, 1995. We received six comments by that date. They were from producers of veterinary biologics. The comments are discussed below.

Analysis of Comments and APHIS' Response

Two commenters supported the proposed rule without change. Four commenters commended the agency for its efforts to streamline and modernize the labeling regulations.

Two commenters suggested that changes to the manufacturer's name and address should be considered minor label changes that would allow label use prior to its submission to and approval by APHIS. APHIS does not agree with this comment. A change to the name and address of the manufacturer is deemed a major label change. Every applicant for a veterinary biologics establishment license must file an APHIS Form 2001, Application for United States Veterinary Biologics Establishment License. The information required by this form includes the name and address of the applicant, all subsidiaries and divisions, and locations of all premises to be used for preparation, testing, and initial shipping. This information is included in the establishment license when issued. A change to the name and address of the manufacturer requires a new APHIS Form 2001 to be filed (9

CFR 102.3(a)(6)) to effect a change in the establishment license before such label changes would be approved.

Also, the name and address of the manufacturer provides consumers with one of the necessary items of identification of a product if they wish to file a consumer complaint about a particular product. APHIS has issued veterinary biologics establishment licenses to 114 manufacturers for some 2300 veterinary biological products, including bacterins, vaccines, and diagnostic test kits. Consumers report complaints of veterinary biological products to the licensee, Veterinary Biologics Field Operations, other units within APHIS, and to the U.S. Practitioners Reporting System of the American Veterinary Medical Association. The minimum amount of information that these entities need to initiate an investigation of these complaints is the name and address of the manufacturer and the name of the product. For the reasons states above, this information must first be submitted to APHIS before such information appears on the label.

APHIS is aware that mergers and acquisitions often result in the need to submit hundreds of new labels to change the manufacturer's name and address. This final rule will reduce the number of new labels that will need to be submitted in such cases, but will not permit the use of such labels until they have been reviewed and filed by APHIS. APHIS is aware of the inconvenience that this may cause, but believes that this is a necessary requirement. No change to the regulations is made in response to this comment.

The same commenter also requested that changes to the distributor's name, address, and phone number be included under minor label changes. APHIS does not agree. Products sold through a distributor are often traced under the distributor's name, address, and phone number. Thus, APHIS should be aware of and have on file the most current name, address, and phone number of distributors of biological products and not have to wait 60 days for the submission of this information. No change is made in response to this comment.

In addition, the commenter requested that label changes to type font, font size (so long as the size change does not cause any element to overshadow the true name), and trade name be included among minor label changes. Again, APHIS does not agree. Changes to the type font often lead to a difference in interpretation of the meaning of ''prominence'' in that no element on a label may be more ''prominent'' than the true name. Trade names often allow consumers to recognize a specific product. Trade names also may suggest special qualities or ingredients about products which may render the product label false or misleading. Thus, APHIS feels that a pre-review of trade names will assure that labels are not false and misleading. Consumer contacts or reports about biological products are often based on a product's trade name. APHIS is informed of new trade names through the label approval process. If new trade names are used on product labels before approval, APHIS may not be able to identify the product if the product becomes involved in a complaint. No change to the regulations is made in response to this comment.

One commenter remarked that the master label concept will lead to the submission of master labels for all labels in order to take advantage of the provision allowing label use prior to APHIS approval. The commenter concluded that this would lead to more paperwork submission for the firm. This is not the intent of the rule. The proposed rule may have been drawn too narrowly in its focus on master labels and the use of certain labels prior to approval by APHIS. There is no good reason why the provision allowing the use of certain labels prior to APHIS approval should be restricted to labels filed as master labels. In response to the commenter, we are amending the proposal so that it will apply to either ''approved labels or master labels.'' The introductory paragraph in § 112.5 is also amended to be consistent with this change. This amendment will make unnecessary the resubmission of currently approved labels for reapproval as master labels to take advantage of the provision of allowing use prior to approval, will avoid the additional paperwork that could result, and is consistent with our original intent.

One commenter requested that the rule continue to specify that ''at least'' a certain number of copies of labels be submitted for approval since manufacturers sometimes need additional approved copies of labels when machine copies are not acceptable. In response to this comment, the proposed rule merely specifies the minimum number of copies that need to be submitted to APHIS for review and approval. APHIS will process additional copies if requested by a manufacturer. No change to the regulations is made in response to this comment.

Finally, one commenter believed that there was a discrepancy between the proposed rule and Veterinary Services Memorandum 800.54, dated August 31, 1988, concerning small labels. APHIS does not agree. APHIS' intent in this rule is to have the master label be based on the smallest size label that is identical in text to that of all other size labels. In the case of labels that are too small for full instructions for use, these exceptionally small labels may differ in text from the labels referred to under the rule and would not qualify as master labels. Such labels would be required to be submitted separately for review. No change to the regulations is made in response to this comment.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposal as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

Pursuant to requirements set forth in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), APHIS has considered the economic impact on small entities.

The rule amends the regulations for the review and approval of veterinary biological product labels by providing for a master label system. The current regulations in part 112 require the submission and approval of all labels for each biological product to be marketed. The approval of the smallest size container label for the product as a prototype master label would reduce the need for licensees producing veterinary biologicals to submit for approval additional copies of labels for each size of the product.

The approval of a master label eliminates the need to submit labels for larger container sizes of the same product, provided that such labels are identical to the master label, except for physical dimensions, and provided that additional container sizes are authorized in a filed Outline of Production.

This rule also allows certain specified minor revisions to be made in labels for products with approved labels or master labels and the revised labels used without prior written approval from APHIS with the provision that new labels or master labels be submitted to APHIS for review and approval within 60 days use of the revised label.

One effect of the rule will be to reduce the number of copies of labels that need to be submitted and reviewed. Most biological products are marketed in two or three different size containers. Currently, each label for each container

must be submitted for approval. Under the master label system, only labels for the smallest size container need to be submitted, thus reducing by two to three-fold the number of labels that need to be submitted by manufacturers for review by APHIS. Another effect will be to eliminate the delay required in obtaining APHIS approval prior to the use of labels with certain specified minor changes.

The rule will not have any adverse economic impact since the submission of product labels for approval is already required under § 112.5 of the regulations. Section 112.5 currently specifies that all labels shall be reviewed and approved prior to use. The amendments will simplify the process of label approvals and reduce the time and expense needed to get a product to market, particularly in the case of certain minor revisions of labels.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule would 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 a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB), and there are no new requirements. The assigned OMB control number is 0579–0013.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials (See 7 CFR part 3015, subpart V.)

List of Subjects

9 CFR Part 101

Animal biologics.

9 CFR Part 112

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, 9 CFR parts 101 and 112 are amended as follows:

PART 101—DEFINITIONS

1. The authority citation for part 101 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.2(d).

2. Section 101.4 is amended by adding a new paragraph (h) to read as follows:

§ 101.4 Labeling terminology.

* * * * *

(h) *Master label.* The finished carton, container, or enclosure label for the smallest size final container that is authorized for a biological product, that serves as the Master template label applicable to all other size containers or cartons of the same product that is marketed by a licensee, subsidiary, division, or distributor.

PART 112—PACKING AND LABELING

3. The authority citation for part 112 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.2(d).

4. Section 112.5 is amended as follows:

a. The introductory text is revised to read as set forth below.

b. Paragraph (c) is revised to read as set forth below.

c. Paragraphs (d)(1) is revised.

d. Paragraph (d)(2)(iii)(*a*) is revised to read as set forth below.

e. Paragraph (d)(3)(ii)(*a*) is revised to read as set forth below.

f. In § 112.5, paragraph (d)(2)(iii)(*b*) is redesignated paragraph (d)(2)(iii)(B), paragraph (d)(3)(i)(*a*) is redesignated paragraph (d)(3)(i)(A), paragraph (d)(3)(i)(*b*) is redesignated paragraph (d)(3)(i)(B), and paragraph (d)(3)(ii) is revised to read as set forth below.

g. Paragraph (d)(3)(iii) is revised to read as set forth below.

h. Paragraph (d)(4) is revised to read as set forth below.

i. Paragraph (g) is added to read as set forth below.

j. Section 112.5 is amended by adding at the end of the section an OMB control number as set forth below.

§ 112.5 Review and approval of labeling.

Labels used with biological products prepared at licensed establishments or imported for general distribution and sale must be submitted to the Animal and Plant Health Inspection Service for review for compliance with the regulations and approval in writing prior to use, except as provided in paragraph (c) of this section and under the master label system provided in paragraph (d) of this section.

* * * * *

(c) (1) Labels must be submitted to the Animal and Plant Health Inspection Service for review and written approval. Only labels which are approved as provided in § 112.5(d) may be used. When changes are made in approved labels, the new labels shall be subject to review and approval before use: *Provided,* That certain minor changes may be made in labels for products with approved labels or master labels, and the revised labels may be used prior to review by APHIS, with the provision that a new label or master label bearing these changes is submitted to APHIS for review and written approval within 60 days of label use, and that such minor changes do not render the product mislabeled or the label false and misleading in any particular.

(2) Minor label changes that may be made under the provision for products with approved labels or master labels are:

(i) Changes in the physical dimensions of the label provided that such change does not affect the legibility of the label;

(ii) Change in the color of label print, provided that such change does not affect the legibility of the label;

(iii) The addition or deletion of a Trade Mark (TM) or Registered (R) symbol;

(iv) The correction of typographical errors;

(v) Adding or changing control numbers of bar codes; and

(vi) Revising or updating logos.

* * * * *

(d) (1) * * *

(i) For label sketches, submit two copies of each sketch of a final container label, carton label, and enclosure. Sketches must be legible, and must include all information specified in § 112.2. One copy of each sketch will be returned with applicable comments, and one copy will be held on file by APHIS for no more than one year after processing, until replaced by a finished label: *Provided,* That sketches submitted in support of an application for a license or permit shall be held as long as the application is considered active.

(ii) For master label sketches, submit for each product two copies of each sketch of an enclosure, label for the smallest size final container, and carton label; *Provided,* That labels for larger

size containers and/or cartons that are identical, except for physical dimensions, need not be submitted. One copy of each master label sketch will be returned with applicable comments, and one copy will be held on file by APHIS for one year after processing, until replaced by a finished master label that is submitted according to § 112.5(d)(1)(iii): *Provided,* That master label sketches submitted in support of an application for license or permit shall be held as long as the application is considered active.

(iii) For finished labels, submit three copies of each finished final container label, carton label, and enclosure: *Provided,* That when an enclosure is to be used with more than one product, one extra copy shall be submitted for each additional product. Two copies of each finished label will be retained by APHIS. One copy will be stamped and returned to the licensee. Labels to which exceptions are taken shall be marked as sketches and handled under § 112.5(d)(1)(i).

(iv) For finished master labels, submit for each product three copies each of the enclosure and the labels for the smallest size final container and carton. Labels for larger sizes of containers or cartons of the same product that are identical, except for physical dimensions, need not be submitted. Such labels become eligible for use, concurrent with the approval of the appropriate finished master label: *Provided,* That the marketing of larger sizes of final containers is approved in the filed Outline of Production, and the appropriate larger sizes of containers or cartons are identified on the label mounting sheet. When a master label enclosure is to be used with more than one product, one extra copy for each additional product shall be submitted. Two copies of each finished master label will be retained by APHIS. One copy will be stamped and returned to the licensee. Master labels to which exceptions are taken will be marked as sketches and handled under § 112.5(d)(1)(ii).

* * * * *

(2) * * *

(iii)(A) When two final containers are packaged together in a combination package, the labels for each shall be mounted on the same sheet of paper and shall be treated as one label. For diagnostic test kits, the labels for use on the individual reagent containers to be included in the kit shall be mounted together on a single sheet of paper, if possible; if necessary, a second sheet of paper may be used. The carton label and enclosure shall be mounted on separate individual sheets.

* * * * *

(3) * * *

(ii)(A) Designation of the specimen as a label or master label: sketch, final container label, carton label, or enclosure.

(B) If two final container labels or multiple parts are on one sheet, each shall be named, and the label or part being revised shall be designated.

(iii) Size of package (dose, ml., cc., or units) for which the labels or enclosures are to be used.

(4) To appear on the bottom of each page: The reason for and information relevant to the submission shall be stated in the lower left hand corner as:

(i) Master label dose sizes approved for code _____.

(ii) Replacement for label, master label, and/or sketch No. _____.

(iii) Reference to label or master label No. _____.

(iv) Addition to label No. _____.

(v) License Application Pending _____.

(vi) Foreign Language copy of Label No. _____.

* * * * *

(g) At the time of an inspection, or when requested by APHIS, licensees or permittees shall make all labels and master labels, including labels approved for use but exempted from filing under the master label system, available for review by authorized inspectors. Such labels shall be identical to the approved label or master label except for physical dimensions, reference to recoverable volume or doses and/or certain minor differences permitted in accordance with § 112.5(c).

(Approved by the Office of Management and Budget under control number 0579–0013)

5. In § 112.7, paragraphs (c)(2) and (d)(6) are revised to read as follows:

§ 112.7 Special additional requirements.

* * * * *

(c) * * *

(2) Subsequent revaccination as determined from the results of duration of immunity studies conducted as prescribed in § 113.209, paragraph (b) or (c), or both.

* * * * *

(d) * * *

(6) Subsequent revaccination as determined from the results of duration of immunity studies conducted as prescribed in § 113.312, paragraph (b) or (c), or both.

* * * * *

§ 112.7 [Amended]

6. Section 112.7 is amended by adding at the end of the section the following: ''(Approved by the Office of Management and Budget under control number 0579–0013).''

Done in Washington, DC, this 5th day of June 1996.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–14772 Filed 6–10–96; 8:45 am]

BILLING CODE 3410–34–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–NM–112–AD; Amendment 39–9656; AD 96–12–13]

RIN 2120–AA64

Airworthiness Directives; Dornier Model 328 Series Airplanes Equipped with Honeywell GP–300 Guidance and Display Controller

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Dornier Model 328 series airplanes. This action requires modification of certain Honeywell GP–300 guidance and display controllers. This amendment is prompted by reports of smoke and fumes, due to a defective light bulb, emitting from the Honeywell GP–300 guidance and display controller; and a report of failure of the autopilot to disconnect manually. The actions specified in this AD are intended to prevent a defective light bulb from causing a short circuit that emits smoke and fumes into the cockpit; or causing damage to the circuit cards and various components, which may lock the autopilot into the engaged mode. Locking of the autopilot into the engaged mode could lead to the inability of the pilot to disconnect the autopilot, which could result in reduced controllability of the airplane.

DATES: Effective June 26, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 26, 1996.

Comments for inclusion in the Rules Docket must be received on or before August 12, 1996.