regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

Extra Flugzeugbau GMBH: Docket No. 97–CE–93–AD.

Applicability: Models EA–300/S airplanes, serial numbers 01 through 24, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required within the next 100 hours time-in-service (TIS) after the effective date of this AD, unless already accomplished.

To prevent failure of the canopy while the airplane is in flight due to cracked canopy latches, which could result in loss of the canopy and possible loss of control of the airplane, accomplish the following:

(a) Modify all canopy latches or replace all canopy latches with parts of improved design, part number (P/N) PC–23303.8P1 for both front latches and the rear right; and P/N PC–23303.8P2 for the rear left. Accomplish the modifications or replacements in accordance with the *Instructions* section of EXTRA Service Bulletin No. 300–3–94, dated August 3, 1994.

(b) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(c) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(d) All persons affected by this directive may obtain copies of the document referred to herein upon request to EXTRA Flugzeugbau GmbH, Flugplatz Dinslaken, 46569 Hunxe, Germany; or may examine this document at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Note 3: The subject of this AD is addressed in German AD No. 94–258, dated August 25, 1994.

Issued in Kansas City, Missouri, on October 29, 1997.

Mary Ellen A. Schutt,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–29239 Filed 11–4–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Part 303

DEPARTMENT OF THE INTERIOR

Office of Insular Affairs

[Docket No. 971021249–7249–01]

RIN 0625–AA50

Proposed Limit on Duty-Free Insular Watches in Calendar Year 1998

AGENCIES: Import Administration, International Trade Administration, Department of Commerce; Office of Insular Affairs, Department of the Interior.

ACTION: Proposed rule and request for comments.

SUMMARY: This action invites public comment on a proposal to amend the ITA regulations, which govern duty-exemption allocations and duty-refund entitlements for watch producers in the United States' insular possessions (the Virgin Islands, Guam and American Samoa) and the Northern Mariana Islands. The proposed amendments would establish the total quantity and respective territorial shares of insular watches and watch movements which would be allowed to enter the United States free of duty during calendar year 1998 and make a minor adjustment to the verification of shipments.

DATES: Comments must be received on or before December 5, 1997.

ADDRESSES: Address written comments to Faye Robinson, Program Manager, Statutory Import Programs Staff, Room 4211, U.S. Department of Commerce, Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: Faye Robinson, (202) 482–3526, same address as above.

SUPPLEMENTARY INFORMATION: The insular possessions watch industry provision in Section 110 of Public Law 97–446 (96 Stat. 2331) (1983) as amended by Section 602 of Public Law 103–465 (108 Stat. 4991) (1994) additional U.S. Note 5 to chapter 91 of the HTS requires the Secretary of Commerce and the Secretary of the Interior, acting jointly, to establish a limit on the quantity of watches and watch movements which may be entered free of duty during each calendar year. The law also requires the Secretaries to establish the shares of this limited quantity which may be entered from the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands. Regulations on the establishment of these quantities and shares are contained in §§ 303.3 and 303.4 of title 15, Code of Federal Regulations (15 CFR 303.3 and 303.4). The Departments propose to establish for calendar year 1998 a total quantity and respective territorial shares as shown in the following table:

Virgin Islands	2,600,000
Guam	500,000
American Samoa	500,000
Northern Mariana Islands	500,000

Compared to the total quantity established for 1997 (61 FR 55883; October 30, 1996), this amount would be a decrease of 500,000 units. The proposed Virgin Islands territorial share would be reduced by 500,000 and the shares for Guam, American Samoa and the Northern Mariana Islands would not change. The amount we proposed for the Virgin Islands is more than sufficient for the anticipated needs of all the existing producers.

The proposed rule would also modify § 303.6(a). Currently, the Departments are able to verify shipments through the U.S. Customs Service. However, due to informal entry procedures on some shipments or other problems, Commerce is occasionally unable to verify an entry. We propose allowing producers to

provide other means of verification satisfactory to the Secretaries in these situations.

The proposed rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

Regulatory Flexibility Act. In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, the Assistant General Counsel for Legislation and Regulation has certified to the Chief Counsel, Small Business Administration, that the proposed rule will not have a significant economic impact on a substantial number of small entities. This is because the rulemaking is primarily to make technical changes.

Paperwork Reduction Act. This rulemaking involves information collection activities subject to the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* which is currently approved by the Office of Management and Budget under control number 0625–0134. The amendments would have no effect on the information burden on the public.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information unless it displays a currently valid OMB Control Number.

It has been determined that the proposed rulemaking is not significant for purposes of Executive Order 12866.

List of Subjects in 15 CFR Part 303

Administrative practice and procedure, American Samoa, Customs duties and inspection, Guam, Imports, Marketing quotas, Northern Mariana Islands, Reporting and recordkeeping requirements, Virgin Islands, Watches and jewelry.

For reasons set forth above, we propose to amend 15 CFR Part 303 as follows:

PART 303—[AMENDED]

§ 303.6 [Amended]

1. Section 303.6(a) is amended by adding to the second to last sentence '', or verified by other means satisfactory to the Secretaries,'' after the words U.S. Customs Service.

§ 303.14 [Amended]

2. Section 303.14(e) is amended by removing ''3,100,000'' and adding ''2,600,000'' in its place.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

Allen Stayman,

Director, Office of Insular Affairs.

[FR Doc. 97–29198 Filed 11–4–97; 8:45 am]

BILLING CODE 3510–DS–M and 4310–93–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. 97N–0435]

Substantial Evidence of Effectiveness of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA), as directed by the Animal Drug Availability Act of 1996 (ADAA), is proposing to amend its new animal drug regulations to further define the term ''substantial evidence.'' The purpose of this proposed regulation is to encourage the submission of new animal drug applications (NADA's) and supplemental NADA's for single ingredient and combination new animal drugs. The proposal also encourages dose range labeling.

DATES: Submit written comments on the proposed rule by February 3, 1998. Submit written comments on the information collection requirements by December 5, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn.: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Herman M. Schoenemann, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

SUPPLEMENTARY INFORMATION:

I. Background

Congress enacted the ADAA (Pub. L. 104–250) on October 9, 1996. The purpose of the ADAA is to facilitate the approval and marketing of new animal drugs and medicated feeds. In furtherance of this purpose, section 2(a) of the ADAA amended section 512(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(d)(3)) to revise the definition of ''substantial evidence.'' Section 2(e) of the ADAA directs FDA to issue proposed regulations to further define the term ''substantial evidence'' in a manner that encourages the submission of NADA's and supplemental NADA's. Section 2(e) also directs FDA to issue proposed regulations to encourage dose range labeling. This proposed regulation further defines substantial evidence and encourages dose range labeling.

Before FDA can approve a new animal drug, FDA must find, among other things, that there is substantial evidence that the new animal drug is effective. The demonstration of effectiveness represents a significant component of drug development time and cost such that the amount and nature of the evidence needed can be an important determinant of whether and when new animal drugs become available to the public. The availability of certain approved new animal drugs for use in livestock, poultry, pets, and other animals is vital to protecting the health of animals and the health of humans who consume the products of food producing animals. The availability of other approved new animal drugs is vital to increasing the efficiency of food production in the United States. Thus, animal and human health and food production are best served by the development of substantial evidence of effectiveness in an efficient manner. The changes made to the definition of ''substantial evidence'' by the ADAA and by the further definition of that term in this proposed rule give FDA greater flexibility to make case-specific scientific determinations regarding the number and types of adequate and well-controlled studies that will provide, in an efficient manner, substantial evidence that a new animal drug is effective.

II. The Statutory Definition of Substantial Evidence

The term ''substantial evidence'' as defined in section 512(d)(3) of the act refers to the number and types of adequate and well-controlled studies needed for a new animal drug to be determined to be effective for the intended uses under the conditions of use prescribed, recommended, or suggested (hereinafter suggested) in its labeling or proposed labeling.