action is warranted to relieve restrictions.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make it effective upon signature. We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. It will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This interim rule amends the Medfly regulations by removing an area in Hillsborough County, FL, from quarantine for Medfly. This action affects the interstate movement of regulated articles from this area. There are approximately 292 small entities that could be affected, including 3 transportation terminals, 65 fruit stands, 36 flea markets, 39 farmers markets, 134 food stores, and 15 garbage service firms.

These small entities comprise less than 1 percent of the total number of similar small entities operating in the State of Florida. In addition, most of these small entities sell regulated articles primarily for local intrastate, not interstate movement, and the sale of these articles would not be affected by this interim rule.

Therefore, termination of the quarantine in Hillsborough County, FL, should have a minimal economic effect on the small entities operating in this area. We anticipate that the economic impact of lifting the quarantine, though positive, will be no more significant than was the minimal impact of its imposition.

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 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.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Incorporation by reference, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, 7 CFR part 301 is amended as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 147a, 150bb, 150dd, 150ee, 150ff, 161, 162, and 164–167; 7 CFR 2.22, 2.80, and 371.2(c).

2. Section 301.78–3, paragraph (c), is revised to read as follows:

§ 301.78–3 Quarantined areas.

* * * * *

(c) The areas described below are designated as quarantined areas:

Mediterranean fruit fly is not known to exist in the continental United States.

Done in Washington, DC, this 17th day of April 1998.

Charles P. Schwalbe,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–10661 Filed 4–21–98; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–CE–98–AD; Amendment 39–10367; AD 98–05–06]

RIN 2120–AA64

Airworthiness Directives; Pilatus Aircraft Ltd. Model PC–12 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This action confirms the effective date of Airworthiness Directive (AD) 98–05–06, which applies to Pilatus Aircraft Ltd. (Pilatus) Model PC–12 airplanes. AD 98–05–06 requires inspecting the elevator for incorrect rivet lengths and installing new rivets if incorrect rivet lengths are found. This AD also requires inspecting the elevator to assure that an excessive gap (more than .004 inches or .1 millimeters (mm)) does not exist in the rivet shanks, and installing a shim between the rib and skin to fill any excessive gap. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Switzerland. The actions specified in this AD are intended to prevent fatigue damage to the elevator, which could result in structural failure and eventual loss of control of the airplane.

EFFECTIVE DATE: May 29, 1998.

FOR FURTHER INFORMATION CONTACT: Mr. Roman T. Gabrys, Aerospace Engineer, Small Airplane Directorate, Airplane Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone: (816) 426–6932; facsimile: (816) 426–2169.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with request for comments in the **Federal Register** on March 3, 1998 (63 FR 10299). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA anticipates that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, was received within the comment period, the regulation would become effective on May 29, 1998. No adverse comments were received, and thus this notice confirms that this final rule will become effective on that date.

Issued in Kansas City, Missouri, on April 14, 1998.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certfication Service.

[FR Doc. 98–10596 Filed 4–21–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket Nos. 75N–183F, 75N–183D, and 80N–0280]

RIN 0910–AA01

Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule stating that certain ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective or are misbranded. FDA is issuing this final rule after considering the reports and recommendations of various OTC drug advisory review panels and public comments on proposed agency regulations, which were issued in the form of a tentative final monograph (proposed rule). Based on the absence of substantive comments in opposition to the agency's proposed nonmonograph status for these ingredients, as well as the failure of interested parties to submit new data or information to FDA under the regulation, the agency has determined that the presence of these ingredients in an OTC drug product would result in that drug product not being generally recognized as safe and effective or would result in misbranding. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Effective October 19, 1998.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 7, 1990 (55 FR 46914), FDA published under § 330.10(a)(7)(ii) (21 CFR 330.10(a)(7)(ii)), a final rule on the status of certain OTC drug Category II and III active ingredients. That final rule declared as not generally recognized as safe and effective certain active ingredients that had been proposed as nonmonograph (Category II or Category III) under the agency's OTC drug review. The periods for submission of comments and new data following the publication of a notice of proposed rulemaking (NPRM) had closed and no significant comments or new data had been submitted to upgrade the status of these ingredients. In each instance, a final rule for the class of ingredients involved had not been published to date.

In the **Federal Register** of May 10, 1993 (58 FR 27636), FDA published a final rule establishing that certain additional active ingredients in OTC drug products are not generally recognized as safe and effective or are misbranded. That final rule included active ingredients from a number of OTC drug rulemakings that were not covered by the November 7, 1990, final rule. (See Table I (58 FR 27636 at 27639 to 27641) for a list of OTC drug rulemakings and active ingredients covered by that final rule.)

At that time, there were other OTC drug review rulemakings for which the period for submission of comments and/or new data was still pending. Those periods have now closed, and there are a number of active ingredients for which no significant comments or new data were submitted. In each instance, a final rule for the class of ingredients involved has not been published to date. This final rule addresses some of the Category II and Category III active ingredients in those classes of ingredients, specifically active ingredients considered in the rulemakings for OTC vaginal contraceptive, first aid antiseptic, and antimicrobial diaper rash drug products.

In the advance notice of proposed rulemaking (ANPRM) for OTC vaginal contraceptive drug products (45 FR 82014, December 12, 1980), the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products placed phenylmercuric acetate and phenylmercuric nitrate in Category II for safety and placed dodecaethylene glycol monolaurate (polyethylene glycol 600 monolaurate), laureth 10S, and methoxypolyoxyethyleneglycol 550 laurate in Category III for efficacy. In the tentative final monograph (TFM) for OTC vaginal contraceptive drug products (60 FR 6892, February 3, 1995), the agency proposed that all of these ingredients be nonmonograph. In response to this TFM (NPRM), the agency received no comments or data relating to the safety and effectiveness of these ingredients.

In the ANPRM for mercury-containing drug products for OTC topical antimicrobial use (47 FR 436, January 5, 1982), the Advisory Review Panel on OTC Miscellaneous External Drug Products placed all mercury compounds in Category II for topical antimicrobial use. This included the following ingredients: Ammoniated mercury; calomel (mercurous chloride); merbromin (mercurochrome); mercuric chloride (bichloride of mercury, mercury chloride); mercufenol chloride (ortho-chloromercuriphenol, ortho-hydroxyphenylmercuric chloride); mercuric salicylate; mercuric sulfide (red mercuric sulfide); mercuric oxide, yellow; mercury; mercury chloride; mercury oleate; nitromersol; para-chloromercuriphenol; phenylmercuric nitrate; thimerosal; vitromersol; and zyloxin. In the NPRM for OTC first aid antiseptic drug products (56 FR 33644, July 22, 1991), the agency proposed that all of these ingredients were either Category II or Category III. In response to this NPRM, the agency received no comments or data relating to the safety and effectiveness of these ingredients.

In an amendment to the proposed rulemaking for OTC topical antimicrobial drug products (55 FR 25246, June 20, 1990), the agency proposed that p-chloromercuriphenol and all other ingredients containing mercury were Category II for the treatment and prevention of diaper rash. In response to this NPRM, the agency received no comments or data relating to the safety and effectiveness of these ingredients.

II. Affected Rulemakings and Category II and III Ingredients

Table I of this document lists the titles and docket numbers of the specific rulemakings containing active ingredients that are addressed in this document, together with the publication dates of the ANPRM and the NPRM, as well as the closing dates for comments and submission of new data for each rulemaking. FDA advises that the active ingredients discussed in this document (see Table II of section II of this document) will not be included in the relevant final monographs because they have not been shown to be generally recognized as safe and effective for their intended use. The agency further advises that these ingredients should be eliminated from OTC drug products 6 months after the date of publication in the **Federal Register** of this final rule regardless of whether further testing is undertaken to justify future use.