

**Note 4:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

#### Special Flight Permits

(e) 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.

#### Incorporation by Reference

(f) The actions shall be done in accordance with Bombardier Alert Service Bulletin A8-32-145, Revision 'A', dated December 3, 1999. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**Note 5:** The subject of this AD is addressed in Canadian airworthiness directive CF-99-22, dated August 30, 1999.

#### Effective Date

(g) This amendment becomes effective on May 7, 2001.

Issued in Renton, Washington, on March 22, 2001.

**Donald L. Riggan,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 01-7700 Filed 3-30-01; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 99-NE-43-AD; Amendment 39-12143; AD 99-18-18 R1]

RIN 2120-AA64

#### Airworthiness Directives: Dowty Aerospace Propellers Model R381/6-123-F/5 Propellers, Correction

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule; correction.

**SUMMARY:** This document makes a correction to Airworthiness Directive (AD) 99-18-18 R1 applicable to Dowty Aerospace Propellers model R381/6-123-F/5 propellers that was published in the **Federal Register** on March 15, 2001 (66 FR 15022). Under PART 39—

AIRWORTHINESS DIRECTIVES, in paragraph 2, a part of that sentence was inadvertently repeated. Also, the amendment number was inadvertently omitted from one of the two locations where it appears in the regulatory section. This document corrects these typographical errors. In all other respects, the original document remains the same.

**EFFECTIVE DATE:** April 19, 2001.

**FOR FURTHER INFORMATION CONTACT:** Kirk Gustafson, Aerospace Engineer, Boston Aircraft Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238-7190, fax (781) 238-7199.

**SUPPLEMENTARY INFORMATION:** A final rule airworthiness directive (FR Doc. 01-5735) applicable to Dowty Aerospace Propellers model R381/6-123-F/5 propellers was published in the **Federal Register** on March 15, 2001 (66 FR 15022). The following correction is needed:

#### § 39.13 [Corrected]

On page 15023, in the third column, under PART 39—AIRWORTHINESS DIRECTIVES, amendatory instruction 2 and the heading of AD 99-18-18 R1 are corrected to read as follows:

2. Section 39.13 is amended by removing Amendment 39-11284 (64 FR 47661, September 1, 1999), and by adding a new airworthiness directive (AD), Amendment 39-12143 to read as follows:

**99-18-18 R1, Dowty Aerospace Propellers:**  
Amendment 39-12143. Docket 99-NE-43-AD. Revises AD 99-18-18, Amendment 39-11284.

\* \* \* \* \*

Issued in Burlington, MA, on March 23, 2001.

**David A. Downey,**

*Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 01-7962 Filed 3-30-01; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 172

[Docket No. 99F-2082]

#### Food Additives Permitted for Direct Addition to Food for Human Consumption; Food Starch-Modified by Amyolytic Enzymes

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of food starch-modified by amyolytic enzymes. This action is in response to a petition filed by the National Starch and Chemical Co.

**DATES:** This rule is effective April 2, 2001. Submit written objections and requests for a hearing by May 2, 2001.

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

**FOR FURTHER INFORMATION CONTACT:** Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3072.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In a notice published in the **Federal Register** on July 2, 1999 (64 FR 36021), FDA announced that a food additive petition (FAP 9A4674) had been filed by the National Starch and Chemical Co., 10 Finderne Ave., Bridgewater, NJ 08807-0500. The petition proposed to amend the food additive regulations in § 172.892(i) *Food starch-modified* (21 CFR 172.892(i)) to provide for the safe use of food starch-modified by amyolytic enzymes. These amyolytic enzymes include beta-amylase, glucoamylase, isoamylase, and pullulanase. This petitioner proposes to use these amyolytic enzymes as a method of starch hydrolysis in addition to the use of alpha-amylase which is currently approved under § 172.892(i). The petitioner also requested that the limitation on dextrose equivalent (DE) as a measure of starch hydrolysis not be applied to starches hydrolyzed with beta-amylase, glucoamylase, isoamylase, or pullulanase. The petitioner states that standard practice is to measure starch hydrolysis by viscosity and other physiochemical properties rather than by dextrose equivalence which measures the ratio of reducing sugars to total sugars.

##### II. Conclusion

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of beta-amylase, glucoamylase, isoamylase, and pullulanase enzymes to modify food starch is safe and that the enzymes will achieve their intended technical effect. Additionally, the agency is not

imposing the limitation that food starch hydrolyzed by beta-amylase, glucoamylase, isoamylase, or pullulanase enzymes have a DE of less than 20.

Under current § 172.892(i), food starch can only be modified by treatment with alpha-amylase (E.C. 3.2.1.1) to produce a nonsweet nutritive saccharide polymer with a DE of less than 20. However, the agency has concluded that this limitation is not necessary for food starch-modified by the petitioned enzymes, beta-amylase, glucoamylase, isoamylase, and pullulanase, that the agency is now adding to § 172.892(i). Therefore, the agency concludes that the regulations in § 172.892(i) should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

**III. Environmental Impact**

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 9A4674 (64 FR 36021). No new

information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

**IV. Paperwork Reduction Act of 1995**

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

**V. Objections**

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by May 2, 2001. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the

objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 172**

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

**PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION**

1. The authority citation for 21 CFR part 172 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.892 is amended by revising the introductory text of paragraph (i) and in the table in paragraph (i) by alphabetically adding the following entries to read as follows:

**§ 172.892 Food starch-modified.**

\* \* \* \* \*

(i) Food starch may be modified by treatment with the following enzymes:

Enzyme	Limitations
* * * * *	* * * * *
Beta-amylase (E.C. 3.2.1.2)	
Glucoamylase (E.C. 3.2.1.3)	
Isoamylase (E.C. 3.2.1.68)	
Pullulanase (E.C. 3.2.1.41)	

Dated: March 26, 2001.  
**Janice F. Oliver,**  
*Deputy Director, Center for Food Safety and Applied Nutrition.*  
 [FR Doc. 01-8060 Filed 3-30-01; 8:45 am]  
**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Food and Drug Administration**  
**21 CFR Parts 510 and 529**  
**New Animal Drugs; Change of Sponsor**  
**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Final rule.  
**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved abbreviated new animal drug

application (ANADA) from Inhalon Pharmaceuticals, Inc., to Minrad, Inc.  
**DATES:** This rule is effective April 2, 2001.  
**FOR FURTHER INFORMATION CONTACT:** Norman J. Turner, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0214.  
**SUPPLEMENTARY INFORMATION:** Inhalon Pharmaceuticals, Inc., P.O. Box 21170, Lehigh Valley, PA 18002, has informed FDA that it has transferred to Minrad, Inc., 836 Main St., 2d floor, Buffalo, NY 14202, ownership of, and all rights and interests in, ANADA 200-141 for Isoflurane, USP. Accordingly, the