

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.

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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

agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) and § 529.1186 (21 CFR 529.1186) to reflect the transfer of ownership.

In addition, Minrad, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, § 510.600(c) is being amended to add entries for the firm. Since Inhalon Pharmaceuticals, Inc., no longer is the sponsor of any approved new animal drug application, their drug labeler code (060307) is being reassigned to Minrad, Inc., as requested. This drug labeler code was removed from § 529.1186(b) in error (60 FR 40455, August 9, 1995), and it is being added at this time.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability."

Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 529 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for "Inhalon Pharmaceuticals, Inc.," and by alphabetically adding an entry for "Minrad, Inc.," and in the table in paragraph (c)(2) by revising the entry for "060307" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

*	*	*	*	*
(c)	*	*	*	
(1)	*	*	*	

Firm name and address					Drug labeler code				
*	*	*	*	*	*	*	*	*	*
Minrad, Inc.,	836 Main St.,	2d floor,	Buffalo, NY	14202	060307				
*	*	*	*	*	*	*	*	*	*
(2)									
Drug labeler code					Firm name and address				
*	*	*	*	*	*	*	*	*	*
060307					Minrad, Inc.,	836 Main St.,	2d floor,	Buffalo, NY	14202
*	*	*	*	*	*	*	*	*	*

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.1186 [Amended]

4. Section 529.1186 *Isoflurane* is amended in paragraph (b) by removing "and 059258" and adding in its place "059258, and 060307".

Dated: March 2, 2001.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 01-8059 Filed 3-30-01; 8:45 am]

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DEPARTMENT OF STATE

Bureau of Consular Affairs\

22 CFR Part 41

[Public Notice 3627]

RIN 1400-AA97

Visas: Nonimmigrant Visa Fees—Fee Reduction for Border Crossing Cards for Mexicans Under Age 15

AGENCY: Bureau of Consular Affairs, DOS.

ACTION: Final rule.

SUMMARY: This rule amends the Department's regulation regarding the collection of fees for certain Mexican citizens under the age of 15 who are applying in Mexico for a machine-readable combined border crossing card and nonimmigrant visa. The change in the regulation is necessitated by a change in pertinent legislation. The effect of the change is to authorize consular officers

to collect reduced fees in certain instances.

DATES: This rule takes effect on April 2, 2001.

FOR FURTHER INFORMATION CONTACT: Pam Chavez, Office of Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520-0106, (202) 663-1206.

SUPPLEMENTARY INFORMATION:

Why Is the Department Amending the Regulation?

Public law 103-236 authorized the Department to collect a surcharge for processing the machine-readable combined border crossing card and nonimmigrant visa. Section 410 of Pub. L. 105-277 reduced the fee for certain Mexican citizens under the age of 15, if the application is made in Mexico by a person who has at least one parent or guardian who has a visa or is applying for a machine-readable combined border crossing card and nonimmigrant visa. The Department is, therefore, amending