Street, Kansas City, Missouri 64106; telephone: (816) 426–3408.

SUPPLEMENTARY INFORMATION: On January 20, 1998, the FAA published in **Federal Register** a direct final rule; request for comments which modified the Class E airspace at Columbus Municipal Airport, NE (FR Doc. 98–1230, 63 FR 2887, Airspace Docket No. 97–ACE–32). The effective date of the document is amended to coincide with the chart change date. After careful review of all available information related to the subject presented above, the FAA has determined that air safety and the public interest require adoption of the rule. The FAA has determined that these corrections will not change the meaning of the action nor add any additional burden on the public beyond that already published. This action amends and confirms the effective date of the direct final rule.

The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes 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, were received within the comment period, the regulation would become effective on April 23, 1998, the effective date as herein amended. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Correction

In rule FR Doc. 98–1230 published in the **Federal Register** on January 20, 1998, 63 FR 2887, make the following correction to the Columbus Municipal Airport, NE, Class E airspace designation incorporated by reference in 14 CFR 71.1:

§ 71.1 [Corrected]

On page 2887 in the second column, after **DATES**, correct ''April 20, 1998,'' to read, ''April 23, 1998.''

Issued in Kansas City, MO, on February 26, 1998.

Bryan H. Burleson,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98–7906 Filed 3–25–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–ACE–20]

Amendment to Class E Airspace; Marshall Army Airfield, Fort Riley, KS

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This notice confirms the effective date of a direct final rule which revises Class E airspace at Marshall Army Airfield, Fort Riley, KS.

DATES: The direct final rule published at 63 FR 2885 is effective on 0901 UTS, April 23, 1998.

FOR FURTHER INFORMATION CONTACT:

Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone: (816) 426–3408.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on January 20, 1998 (63 FR 2885). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes 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, were received within the comment period, the regulation would become effective on April 23, 1998. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO on February 23, 1998.

Christopher R. Blum,

Acting Manager, Air Traffic Division Central Region.

[FR Doc. 98–7904 Filed 3–25–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 91G–0451]

Direct Food Substances Affirmed as Generally Recognized as Safe; Maltodextrin Derived From Rice Starch

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that maltodextrin derived from rice starch is generally recognized as safe (GRAS). This action is in response to a petition filed by Zumbro, Inc.

DATES: Effective March 26, 1998. The Director of the Office of the **Federal Register** approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, of a certain publication at 21 CFR 184.1444, effective March 26, 1998.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3071.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in § 170.35 (21 CFR 170.35), Zumbro, Inc., Rt. 1, Box 3, Hayfield, MN 55940, submitted a petition (GRASP 2G0380) proposing that maltodextrin derived from rice starch be affirmed as GRAS for use as a direct food ingredient.

FDA published a notice of filing of this petition in the **Federal Register** of April 23, 1992 (57 FR 14839), and gave interested parties an opportunity to submit comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. FDA received no comments in response to that notice.

II. Standards for GRAS Affirmation

Under § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of food substances. The basis of such views may be either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, through

experience based on common use in food (§ 170.30(a)). General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive, and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (21 CFR 170.30(b)). General recognition of safety through experience based on common use of a substance in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive, and ordinarily is to be based upon generally available data and information concerning the pre-1958 history of use of the substance in food (§ 170.30(c)(1)).

III. Safety Evaluation

FDA has evaluated the petition submitted by Zumbro, Inc., (GRASP 2G0380) on the basis of scientific procedures to determine whether the use of maltodextrin derived from rice starch is GRAS. In addition to evaluating the data in the petition, FDA also has considered published articles in scientific journals along with other available information in its review. The agency concludes, based upon scientific procedures, that the information presented in the petition, and other published and unpublished information, support a determination that the use of maltodextrin derived from rice starch is GRAS.

Data in the petition, along with other information in the agency's files, demonstrate that rice starch is chemically equivalent to corn starch or potato starch. Additionally, the hydrolysis products made from these starch sources, including maltodextrins, are essentially equivalent. Thus, maltodextrin derived from rice starch is equivalent in all material respects to maltodextrin derived from corn starch or potato starch, both of which have been affirmed as GRAS (§ 184.1444 (21 CFR 184.1444)).

A. Evidence of Chemical Equivalency of Potato Starch and Corn Starch to Rice Starch

Starch is the reserve carbohydrate in tubers such as potatoes, in grains such as rice, corn, or barley, in seeds, and in many fruits. As early as 1811, scientists had determined that food starches from various plant sources were essentially equivalent (Ref. 1). All food starches, regardless of the plant source, are composed of chemically equivalent polymeric forms of alpha-bond-linked glucose units (Ref. 2). Starch consists of polymers of amylose and amylopectin polysaccharides (Refs. 1 and 3). The relative proportions of amylose and amylopectin are characteristic of the plant species from which the starch is derived (Refs. 3 and 4).

Because food starches derived from different plant sources are equivalent in all material respects (Ref. 1), FDA's food additive regulation for modified food starch (21 CFR 172.892) does not specify that any particular source of food starch be used to manufacture the additive. In the **Federal Register** of April 1, 1985 (50 FR 12821) (Ref. 5), FDA published a proposal to affirm that rice starch (as well as several other starches) is GRAS for use in food. FDA has not issued a final rule in that rulemaking. In addition, the Committee on Food Chemicals Codex of the National Academy of Sciences has published a monograph on maltodextrin stating that it may be obtained from any edible starch (Ref. 6). Like FDA's food additive regulation for modified food starch, the monograph does not require that the starch be derived from any particular plant source.

Producing maltodextrin by the degradation of starch requires the formation of intermediate breakdown products called dextrins, which result from the partial hydrolysis of starch with mineral acids or amylase (Refs. 2 and 7). Further hydrolysis of the starch dextrins yields maltodextrins.

Dextrins are affirmed as GRAS under 21 CFR 184.1277 and can be prepared by partially hydrolyzing the starch in corn, potato, arrowroot, wheat, rice, or other starch sources. It has been common industrial practice to use a wide variety of starch sources in manufacturing commercial dextrin products (Refs. 2 and 7). During digestion, acid and enzymatic processes in the stomach convert the starch macromolecules to smaller molecules, such as maltodextrin, and eventually to glucose. This digestion process is similar to the commercial process used to produce glucose and fructose, which are GRAS starch-based sweeteners presently used in foods (Ref. 7). (See corn sugar, 21 CFR 184.1857; corn syrup, 21 CFR 184.1865; and high fructose corn syrup, 21 CFR 184.1866).

Starch hydrolysates below 20 dextrose equivalents (D.E.) are classified as maltodextrins (Refs. 8 and 9). Specifications for maltodextrins are listed in the Food Chemicals Codex, 4th ed., (1996) (Ref. 6). Equivalent maltodextrin products result from equivalent hydrolysis of edible starch sources (Ref. 10). Because corn starch, potato starch, and rice starch are essentially equivalent, the products of hydrolysis, from simple glucose molecules to more complex starch hydrolysates, such as dextrins and maltodextrins, are essentially equivalent in terms of chemical, physical, and organoleptic properties.

B. Corroborative Evidence of Chemical Equivalency

The petitioner has submitted data to demonstrate the equivalency of maltodextrin derived from rice starch with maltodextrin derived from tapioca and potato starches, based upon chemical properties such as dextrose equivalents (D.E.) and commercial uses (Refs. 11 and 12). Additionally, the petitioner provided carbohyrate profiles for corn maltodextrin and rice maltodextrin that demonstrate that the range of carbohydrate composition in maltodextrins derived from corn starch is virtually identical to that for maltodextrins derived from rice starch (Ref. 13). Moreover, based upon information submitted by the petitioner and on information available in the current scientific literature, FDA concludes (Ref. 10) that rice starch may be considered chemically equivalent to corn starch in regard to the content of the basic chemical components of starch (i.e., amylose and amylopectin) (Refs. 1, 2, 3, 4, 7, 14, and 15).

C. Proposed Use in Food

Information supplied by the petitioner indicates that maltodextrin derived from rice starch will be used as a replacement for maltodextrin derived from corn starch or potato starch in the same foods, at essentially the same levels, and for the same technical effects that maltodextrin derived from corn starch or potato starch is now used (Ref. 16). The petitioner indicates that maltodextrins are currently used in a wide range of processed and convenience foods, principally as a filler or carrier for flavorings and intensive sweeteners and as a sweetness reducer or texture modifier. Because maltodextrin derived from rice starch will be used as a replacement for maltodextrin derived from corn starch or potato starch, the exposure of consumers to maltodextrin is not expected to increase.

D. General Recognition of Safety

The agency has determined, based on published information, that the safety of maltodextrin derived from rice starch is generally recognized by food safety experts. Foremost in the support of safety is published information that shows that corn starch, potato starch, and rice starch are chemically equivalent, and therefore, maltodextrin

derived from rice starch is equivalent to the maltodextrin derived from corn starch or potato starch. Thus, maltodextrin derived from rice starch presents no more of a safety concern than maltodextrin derived from corn starch or potato starch, both of which have been affirmed as GRAS.

Moreover, many countries, including those represented by the European Starch Association (Ref. 9), recognize ''food starches,'' including rice starch, as a suitable raw material for maltodextrin production. Furthermore, the Food and Agriculture Organization/World Health Organization and the Joint Expert Committee on Food Additives (JECFA) (Refs. 17 and 18) recognizes maltodextrin as an intermediate product in the production of enzyme-treated starches, a process that JECFA has stated results in the production of normal (meaning safe) food constituents. JECFA does not restrict the sources of food starches used in the production of products such as maltodextrins. JECFA also does not require toxicological testing of products such as maltodextrins that are produced from enzyme-treated starches. Finally, as noted in section III.A. of this document, the agency has proposed to find that rice starch is GRAS (Ref. 5).

The agency concludes that maltodextrin derived from rice starch is chemically and functionally equivalent to maltodextrin derived from edible starch from other sources (Ref. 10). No increase in exposure to maltodextrin would be expected due to the substitution of one source for the other. Because rice starch is already a significant constituent of the typical diet (Ref. 5), the agency does not believe that consumption of maltodextrin derived from rice would cause a dietary concern (Ref. 19).

E. Specifications

The agency has reviewed the specifications for maltodextrin published in the Food Chemicals Codex, 4th ed. (1996), pp. 239 and 240, and it finds that they are acceptable for maltodextrin derived from edible starches. Therefore, the agency is adopting the specifications for maltodextrin derived from edible starches for maltodextrin derived from rice starch.

IV. Conclusions

The agency has evaluated the information in the petition, along with other available data, and has reached the following conclusions:

(1) Rice starch is chemically equivalent to corn and potato starch.

(2) Maltodextrin derived from rice starch is chemically equivalent to maltodextrin derived from corn starch and potato starch, both of which are currently affirmed as GRAS for food use without restriction under § 184.1444.

(3) When maltodextrin derived from rice starch is manufactured according to the methods specified in § 184.1444, for corn and potato starch, there is general recognition among qualified experts that the use of maltodextrin derived from rice starch in food is safe.

Based upon the evaluation of published information, corroborated by unpublished data and information, i.e., based upon scientific procedures (§ 170.30(b)), the agency concludes that maltodextrin derived from rice starch is GRAS for use as a replacement for maltodextrin derived from corn or potato starch. Therefore, the agency is affirming that maltodextrin derived from rice starch is GRAS when used in accordance with good manufacturing practice (21 CFR 184.1(b)(1)).

V. Environmental Effects

The agency has determined under 21 CFR 25.32(f) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis for Executive Order 12866

FDA has examined the impacts of this final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In addition, the agency has determined that this final rule is not a major rule for the purpose of congressional review.

The primary benefit of this action is to remove uncertainty about the regulatory status of the petitioned substance. No compliance costs are associated with this final rule because no new activity is required and no current or future activity is prohibited by this rule.

VII. Regulatory Flexibility Analysis

FDA has examined the impact of this final rule under the Regulatory Flexibility Act. The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Federal agencies to consider alternatives that would minimize the economic impact of their regulations on small entities. FDA finds that this final rule will not have a significant economic impact on a substantial number of small entities.

No compliance costs are associated with this final rule because no new activity is required and no current or future activity is prohibited. Accordingly, under the Regulatory Flexibility Act, 5 U.S.C. 605(b), the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

VIII. Effective Date

As this rule recognizes an exemption from the food additive definition in the Federal Food, Drug, and Cosmetic Act, and from the approval requirements applicable to food additives, no delay in effective date is required by the Administrative Procedure Act (5 U.S.C. 553(d)). The rule will therefore be effective immediately (5 U.S.C. 553(d)(1)).

IX. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

1. Wolfrom, M. L., and H. El Khadem, ''Chemical Evidence for the Structure of Starch,'' *Starch: Chemistry and Technology*, edited by R. L. Whistler, and E. F. Paschall, Academic Press, Inc., New York, pp. 251–278, 1965.

2. ''Starch Hydrolysis Products: An Introduction and History,'' *Starch Hydrolysis Products, Worldwide Technology, Production, and Applications*, edited by F. W. Schenck and R. E. Hebeda, VCH Publishers, Inc., New York, pp. 1–21, 1992.

3. ''Evaluation of the Health Aspects of Starch and Modified Starches as Food Ingredients,'' Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1979.

4. Young, A. H., ''Fractionation of Starch,'' *Starch*, 2d ed., edited by R. L. Whistler, and E. F. Paschall, Academic Press, Inc., New York, pp. 249–283, 1984.

5. ''Unmodified Food Starches and Acid-Modified Starches; Proposed Affirmation of GRAS Status as Direct and Indirect Human Food Ingredients,'' 50 FR 12821, April 1, 1985.

6. Food Chemicals Codex, 4th ed., National Academy Press, Washington, DC, pp. 239 and 240, 1996.

7. Evans, R. B., and O. B. Wurzburg, ''Production and Use of Starch Dextrins,'' *Starch: Chemistry and Technology*, vol. 2, edited by R. L. Whistler, and E. F. Paschall, Academic Press, Inc., New York, pp. 253–278, 1967.

8. ''Food Additives and Contaminants Committee Report on Modified Starches,'' United Kingdom Ministry of Agriculture, Fisheries and Food, FAC/REP/31, Her Majesty's Stationery Office, London, p. 5, 1980.

9. ''Definition of Maltodextrin,'' European Starch Associations, Circular Letter Stex 4/88, February 1988.

10. Memorandum from the Chemistry Review Branch to the Direct Additives Branch, ''Maltodextrin from Rice,'' dated January 13, 1997.

11. ''Paselli SA2,'' *Technical Bulletin*, No. 5.12.33.188EU, AVEBE America, Inc., Princeton, NJ.

12. ''INSTANT N–OIL II,'' *Techical Service Bulletin*, No. 15889–238, National Starch and Chemical Corp., Bridgewater, NJ.

13. Warthesen, J. J., ''Analysis of Saccharides in Low-Dextrose Equivalent Starch Hydrolysates Using High-Performance Liquid Chromatography,'' *Cereal Chemistry*. vol. 61, No. 2, pp. 194 and 195, 1984.

14. Zuber, M. S., ''Genic Control of Starch Development'' *Starch: Chemistry and Technology*, edited by R. L. Whistler and E. F. Paschall, Academic Press, Inc., New York, pp. 45, 61–63, 1965.

15. Whistler, R. L., and J. R. Daniel, ''Starch,'' *Kirk-Othmer's Encyclopedia of Chemical Technology*, 3d ed., vol. 21, edited by J. Brown, C. I. Eastman, Galojuch, et al., John Wiley & Sons, New York, pp. 492–507, 1983.

16. ''Maltodextrin; Proposed Affirmation of GRAS Status as Direct Human Food Ingredient,'' 47 FR 36443, August 20, 1982.

17. ''Specifications for the Identity and Purity of Food Additives and Their Toxicological Evaluation,'' *FAO Nutrition Meetings Report Series*, No. 46 and *WHO Technical Report Series*, No. 445, pp. 13 and 14, 1970.

18. ''Toxicological Evaluation of Some Food Colours, Emulsifiers, Stabilizers, Anti-Caking Agents, and Certain Other Substances,'' *FAO Nutrition Meetings Report Series*, No. 46A, p. 62 and WHO/FOOD ADD./70.36, 1970.

19. Memorandum from the Additives Evaluation Branch, to the Direct Additives Branch, ''GRP 2G0380–GRAS Affirmation Petition for Maltodextrin Derived from Derived Rice: Division of Health Effects Evaluation Review (DHEE; HFS–225),'' dated August 3, 1993.

List of Subjects in 21 CFR Part 184

Food additives, Incorporation by reference.

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 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

2. Section 184.1444 is amended by revising the second sentence in paragraph (a) and by adding paragraph (b)(3) to read as follows:

§ 184.1444 Maltodextrin.

(a) * * * It is prepared as a white powder or concentrated solution by partial hydrolysis of corn starch, potato starch, or rice starch with safe and suitable acids and enzymes.

(b) * * *

(3) Maltodextrin derived from rice starch meets the specifications of the Food Chemicals Codex, 4th ed. (1996), pp. 239 and 240, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

* * * * *

Dated: March 3, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–7894 Filed 3–25–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 600

[Docket No. 93N–0181]

RIN 0910–AA97

Expedited Safety Reporting Requirements for Human Drug and Biological Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of October 7, 1997 (62 FR 52237), to include some conforming amendments that were inadvertently omitted. The final rule amended the expedited safety reporting regulations for human drug and biological products. This action is being taken to ensure the accuracy and consistency of the regulations.

EFFECTIVE DATE: April 6, 1998.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 7, 1997 (62 FR 52237), FDA amended, among other things, its regulations in § 314.80 *Postmarketing reporting of adverse drug experiences* (21 CFR 314.80) and § 600.80 *Postmarketing reporting of adverse experiences* (21 CFR 600.80). In that document, the agency inadvertently omitted conforming amendments to §§ 314.80(k) and 600.80(l) to correct the current cross-references to §§ 314.80(c)(1)(ii) and 600.80(c)(1)(ii). These paragraphs should reference §§ 314.80(c)(1)(iii) and 600.80(c)(1)(iii), respectively. This correction does not, in any way, alter the scope or intent of the October 7, 1997, document.

In final rule FR Doc. 97–26255, published on October 7, 1997 (62 FR 52237), make the following corrections:

§ 314.80 [Corrected]

1. On page 52251, in amendatory instruction 8, in the second column, beginning in line 7, the phrase, ''; and by removing paragraph (j) and redesignating paragraphs (k) and (l) as paragraphs (j) and (k), respectively'' is corrected to read, ''; by removing paragraph (j), redesignating paragraphs (k) and (l) as paragraphs (j) and (k), respectively; and by revising the last sentence in newly redesignated paragraph (k)''.

2. On page 52252, in the second column, in § 314.80, the last sentence of redesignated paragraph (k) is correctly revised to read as follows:

§ 314.80 Postmarketing reporting of adverse drug experiences.

* * * * *

(k) * * * For purposes of this provision, the term ''applicant'' also includes any person reporting under paragraph (c)(1)(iii) of this section.

§ 600.80 [Corrected]

3. On the page 52252, in the second column, in amendatory instruction 10, beginning in line 5, the phrase, ''; and by removing paragraph (j) and redesignating paragraphs (k), (l), and (m) as paragraphs (j), (k), and (l),