* * * * *

Dated: November 24, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–29476 Filed 12–04–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 182 and 186

[Docket No. 80N–0196]

Japan Wax; Affirmation of GRAS Status as an Indirect Human Food Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm Japan wax as generally recognized as safe (GRAS) as an indirect food ingredient for use as a constituent of cotton and cotton fabrics used in dry food packaging. The safety of this indirect food use of Japan wax has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective December 5, 1995.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

SUPPLEMENTARY INFORMATION:

In the Federal Register of June 1, 1995 (60 FR 28555), FDA published a proposal to affirm the GRAS status of the use of Japan wax as an indirect human food ingredient migrating to food from cotton and cotton fabrics used in dry food packaging. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review and the report of the Select Committee on GRAS Substances (the Select Committee) on Japan wax, as well as documents in the possession of FDA and further evidence of the safety of Japan wax obtained by FDA since publication of the Select Committee's report, have been made available for public review in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

The proposal gave interested parties an opportunity to submit comments. FDA received no comments on its proposal. The agency is, therefore, adopting the proposal without any changes.

Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule that published in the Federal Register of June 1, 1995 (60 FR 28555). No new information or comments have been received that would affect the agency's determination that there is no significant impact on the human environment, and that neither an environmental assessment nor an environmental impact statement is required.

Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses.

The agency finds that this rule is not a significant regulatory action as defined by Executive Order 12866. Furthermore, in accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses, and determined that this rule will have no significant adverse impact on a substantial number of small businesses. FDA has received no new information or comments that would alter its previous determination.

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 December 5, 1995 (5 U.S.C. 553(d)(1)).

List of Subjects

21 CFR Part 182

Food ingredients, Food packaging, Spices and flavorings.

21 CFR Part 186

Food ingredients, Food packaging.

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 parts 182 and 186 are amended to read as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 182 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

§ 182.70 [Amended]

2. Section 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging* is amended by removing the entry for ''Japan wax.''

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. The authority citation for 21 CFR part 186 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

4. New § 186.1555 is added to subpart B to read as follows:

§ 186.1555 Japan wax.

(a) Japan wax (CAS Reg. No. 8001–39–6), also known as Japan tallow or sumac wax, is a pale yellow vegetable tallow, containing glycerides of the C_{19}–C_{23} dibasic acids and a high content of tripalmitin. It is prepared from the mesocarp by hot pressing of immature fruits of the oriental sumac, *Rhus succedanea* (Japan, Taiwan, and Indo-China), *R. vernicifera* (Japan), and *R. trichocarpa* (China, Indo-China, India, and Japan). Japan wax is soluble in hot alcohol, benzene, and naphtha, and insoluble in water and in cold alcohol.

(b) In accordance with paragraph (b)(1) of this section, the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based on the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a constituent of cotton and cotton fabrics used for dry food packaging.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.