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April 6, 1993

FREEDOM OF INFORMATION
ACT REQUEST

Mr. Donnie Grimsley
Director of Division of Freedom of
Information and Public Service
Nuclear Regulatory Commission
Washington, D.C. 20555

FOIA-93-216
Rec'd 4-14-93

Re: FREEDOM OF INFORMATION ACT REQUEST

Dear Sirs:

Pursuant to the Freedom of Information Act, as codified at 5 U.S.C. section 552, I request copies of FDA records related to the enactment of 21 C.F.R. § 121.2543 on August 10, 1964.

For your general information I am enclosing as Attachment "A" a microfiche photocopy of the applicable Federal Register entry from 1964, which I hope will help define the topic of my inquiry.

In particular, I would like to locate a copy of:

1. A petition identified in the Federal Register as "PAP 1297," which was filed by the United States Atomic Energy Commission in support of the enactment of 21 C.F.R. § 121.2543 in 1964.

Without limitation, the following records are also requested:

2. Any reports, filings, submissions or other documents provided by the Chemical Manufacturer's Association or any similar trade association or group related to the enactment of 21 C.F.R. § 121.2543 in 1964.
3. Any reports, filings, submissions or other documents provided by any chemical manufacturer related to the enactment of 21 C.F.R. § 121.2543 in 1964.

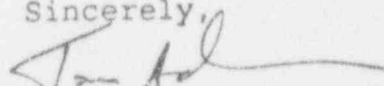
Mr. Donnie Grimsley
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4. Any statistical information, studies, research or demonstration reports, or empirical data relied upon or which pertain to the enactment of 21 C.F.R § 121.2543 in 1964.
5. Any records of hearings, presentations, conferences, or meetings during which the enactment of 21 C.F.R § 121.2543 in 1964 was discussed.
6. Any records of correspondence, notes, memos, or telephone conversations which in any way relate to the enactment of 21 C.F.R § 121.2543 in 1964.
7. Any records or documents relating to the decision of the FDA to enact 21 C.F.R § 121.2543 in 1964.
8. Any reports, filings, or submissions of other relevant material made to or solicited by the FDA related to the enactment of 21 C.F.R § 121.2543 in 1964.
9. Any records or documents relating to the decision of the Atomic Energy Commission to recommend the enactment of 21 C.F.R § 121.2543 in 1964.

I will be happy to pay any administrative expense incurred. If the costs of reproduction exceed \$100.00 I would request that you call me at the number listed above.

I thank you for your kind attention to this matter.

Sincerely,



Thomas W. Andrews

Second Edition—Unabridged, defines "refine" as "To reduce to a fine, unmixed or pure state; to separate from extraneous matter, to free from dross or alloy as metals; to free or cleanse from impurities, as wine, sugar, etc." The same dictionary defines "re" as "again;—used chiefly to form words, especially verbs of action, denoting in general repetition (of the action of the verb) * * *." The combination of these two words, when used to describe oil, would mean, by dictionary definition, that the process of reducing oil to a fine, unmixed or pure state has been repeated.

(c) To the consuming public the word "re-refined" as descriptive of lubricating oil is susceptible of more than one meaning. While members of the trade and more sophisticated consumers might understand that the oil so described had been previously used, to many consumer purchasers who are unaware that oil is reclaimed and resold to the public, "re-refined" could well mean a virgin oil which has been refined more than once. Even when put on notice that the oil has been previously used, many consumers would be led to believe by the word "re-refined" that the oil had been reclaimed and restored to its original condition by a refining process.

(d) The Commission concludes therefore that the word "re-refined" when used alone to describe previously used oil would not adequately inform prospective purchasers that oil so described has been previously used. The Commission further concludes that "re-refined" when coupled with a disclosure that the oil has been previously used would mean to a substantial portion of the consuming public that the oil so described has had the contaminants acquired through previous use removed therefrom by a refining process.

§ 406.5 The rule.

(a) On the basis of the foregoing, the Commission concludes that, in connection with the sale in commerce of lubricating oil composed in whole or in part of previously used oil, the practices of (1) failing to disclose clearly and conspicuously the fact that such oil has been previously used; (2) representing directly or by implication that such oil is new or unused; and (3) representing that such oil has been "re-refined" when the physical and chemical contaminants acquired through use have not been removed by a refining process; have the capacity and tendency to mislead and deceive purchasers and prospective purchasers and to divert business from competitors who truthfully and properly describe and label their products. The Commission further concludes that these practices are violative of section 5 of the Federal Trade Commission Act, and that the public interest in preventing their use is specific and substantial.

(b) Accordingly, for the purpose of preventing such unlawful practices, the Commission hereby promulgates, as a Trade Regulation Rule, its conclusions and determination that in connection with the sale or offering for sale of lubricating oil composed in whole or in part of previously used lubricating oil, in

commerce, as "commerce" is defined in the Federal Trade Commission Act, it constitutes an unfair method of competition and an unfair and deceptive act or practice to:

(1) Represent in any manner that such used lubricating oil is new or unused; or

(2) Fail to disclose clearly and conspicuously that such used lubricating oil has been previously used, in all advertising, sales promotional material and on each front or face panel of the container. For the purpose of this Part 406 the front or face panel means the part (or parts) of the container on which the brand name is usually featured and which is customarily exposed to the view of prospective purchasers when displayed at point of retail sales; or

(3) Use the term "re-refined," or any other word or term of similar import, to describe previously used lubricating oil unless the physical and chemical contaminants acquired through previous use have been removed by a refining process.

(As used in this part, the term "lubricating oil" refers to any oil used for lubricating purposes including but not limited to, motor and transmission oil.)

Effective date. This rule becomes effective January 1, 1965.

Adopted July 28, 1964

By the Commission.

[SEAL] JOSEPH W. SHEA,
Secretary

[P.R. Doc. 64-8218 Filed Aug. 13, 1964; 8:47 a.m.]

Title 10—ATOMIC ENERGY

Chapter I—Atomic Energy Commission

PART 30—LICENSING OF BYPRODUCT MATERIAL

Exemption of Tritium Contained in Balances of Precision

Correction

In P.R. Doc. 64-7958 appearing in the issue for Saturday, August 8, 1964, at page 11445, the word "to" should be inserted preceding the word "balances" in the second line of § 30.14(a).

Title 20—EMPLOYEES' BENEFITS

Chapter III—Social Security Administration, Department of Health, Education, and Welfare

[Regs. 4, further amended]

PART 404—FEDERAL OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE (1950—...)

Quarters of Coverage and Insured Status

Regulations No. 8 of the Social Security Administration, as amended (20 CFR 404.1 et seq.) are further amended as follows:

1. Paragraph (f) of § 404.103 is amended to read as follows:

§ 404.103 Quarter of coverage.

(f) When a quarter of coverage is acquired. Where a calendar quarter is credited as a quarter of coverage under paragraph (b), (c), (d), or (e) of this section the quarter of coverage is acquired as of the first day of such calendar quarter.

2. Paragraph (b) of § 404.108 is amended to read as follows:

§ 404.108 Fully insured status: general.

(b) When fully insured status begins. An individual is fully insured beginning with the first day of the calendar quarter in which he acquires the last required quarter of coverage (see §§ 404.103(f) and 404.109-404.112). Though fully insured under the statutory provisions in effect during a particular period an individual may not be fully insured under the statutory provisions in effect for a prior period and, in such case, no benefits would be payable for such prior period though benefits may be payable currently based on the later requirements. The following §§ 404.109-404.113, set forth the various fully insured status requirements and their period of applicability.

3. *Effective date.* The foregoing amendments shall become effective upon publication in the FEDERAL REGISTER.

[Sec. 208, 213, 214, and 1102 53 Stat. 1368, as amended; 64 Stat. 504, as amended; 64 Stat. 508, as amended; 49 Stat. 847, as amended; sec. 3 of Reorganization Plan No. 1 of 1953; 67 Stat. 18, 631; 42 U.S.C. 405, 413, 414 and 1902]

Dated: July 27, 1964

[SEAL] ROBERT M. BALL,
Commissioner of Social Security.

Approved: August 7, 1964.

ANTHONY J. CELEBREZZE,
Secretary of Health,
Education and Welfare.

[P.R. Doc. 64-8022 Filed Aug. 13, 1964; 8:47 a.m.]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER E—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart F—Food Additives Resulting from Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

PACKAGING MATERIALS FOR USE IN RADIATION PRESERVATION OF PREPACKAGED FOODS

The Commissioner of Food and Drugs, having evaluated the data submitted in a petition (FAP 1297) filed by the U.S. Atomic Energy Commission, Washing-

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Attachment
"A"

son, D.C., 20545, and other relevant material, has concluded that the food additive regulations should be amended to provide for the use of packaging materials that may be safely subjected to irradiation incidental to the radiation preservation of prepackaged foods. Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1788, 21 U.S.C. 348(c)(1)), and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (21 CFR 2.90; 29 P.R. 471), the food additive regulations are amended by adding to Subpart F the following new section:

§ 121.2543 Packaging materials for use in radiation preservation of prepackaged foods.

The packaging materials identified in this section may be safely subjected to irradiation incidental to the radiation preservation of prepackaged foods, subject to the provisions of this section.

(a) The radiation preservation of the food itself shall comply with regulations in Subpart C of this Part 121.

(b) The following packaging materials may be subjected to a dose of irradiation, not to exceed 1 megarad, incidental to the use of gamma radiation in the radiation preservation of prepackaged foods:

(1) Nitrocellulose-coated cellophane complying with § 121.2507.

(2) Glassine paper complying with § 121.2526.

(3) Wax-coated paperboard complying with § 121.2538.

(4) Polypropylene film prepared from polypropylene basic polymer complying with § 121.2561. The finished film may contain adjuvant substances used in compliance with §§ 121.2001 and 121.2811.

(5) Ethylene-alkene-1 copolymer film complying with § 121.2508.

(6) Polyethylene film complying with § 121.2510.

(7) Polystyrene film prepared from styrene basic polymer. The finished film may contain adjuvant substances used in compliance with §§ 121.2001 and 121.2811.

(8) Rubber hydrochloride film prepared from rubber hydrochloride basic polymer having a chlorine content of 36-32 weight percent and having a maximum extractable fraction of 2 weight percent when extracted with n-hexane at reflux temperature for 2 hours. The finished film may contain adjuvant substances used in compliance with §§ 121.2001 and 121.2811.

(9) Vinylidene chloride-vinyl chloride copolymer film prepared from vinylidene chloride-vinyl chloride basic copolymers containing not less than 70 weight percent of vinylidene chloride and having a viscosity of 0.50-1.50 centipoises as determined by ASTM method D 729-67. The finished film may contain adjuvant substances used in compliance with §§ 121.2001 and 121.2811.

Any person who will be adversely affected by the foregoing order may at any

time within 30 days from the date of its publication in the Federal Register file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW, Washington 25, D.C., written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. All documents shall be filed in quintuplicate.

Effective date. This order shall be effective on the date of its publication in the Federal Register.

(Sec. 409(c)(1), 72 Stat. 1788, 21 U.S.C. 348 (c)(1))

Dated August 10, 1964.

Oso P. LARRICK,
Commissioner of Food and Drugs.
(P.R. Doc. 64-2223, Filed Aug. 13, 1964, 8 47 a.m.)

Title 50—WILDLIFE AND FISHERIES

Chapter 1—Bureau of Sport Fisheries

21 C.F.R. § 121.2543 was renumbered
21 C.F.R. § 179.45 in 1977.

Birds

Correction

In Federal Register Document 64-7818, appearing at page 11184 in the issue for Tuesday, August 4, 1964, the first entry under paragraph (b) of § 10.41 should read as follows:

§ 10.41 Seasons and limits on dates and wild pigeons.

(b) Mourning doves—Central Management Unit.

Daily bag limit..... 12*

Title 47—TELECOMMUNICATION

Chapter 1—Federal Communications Commission

[Docket No. 14238, 1967; POC 64-770]

PART 73—RADIO BROADCAST SERVICES

UHF Television Channels; Correction

In the matter of fostering expanded use of UHF Television Channels, Docket

No. 14229; amendment of § 73.606, table of assignments, Television Broadcast Stations (Hanover, New Hampshire), Docket No. 14978.

In a Supplement to the Third Report and Order (POC 64-770) in the above-captioned matter, released on August 3, 1964, the docket number pertaining to Hanover, New Hampshire, in the caption should read "Docket No. 14978" rather than "Docket No. 14970".

Released: August 11, 1964.

FEDERAL COMMUNICATIONS
COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

(P.R. Doc. 64-2230, Filed Aug. 13, 1964, 8 48 a.m.)

Title 42—PUBLIC HEALTH

Chapter 1—Public Health Service, Department of Health, Education, and Welfare

PART 72—INTERSTATE QUARANTINE

Etologic Agents

Notice of proposed rule making, public rule making procedures and postponement of effective date have been omitted as unnecessary in the issuance

to carry out the national defense program, the Surgeon General may approve variations as to the requirements of subparagraphs 1, 2 and 3 of this paragraph if upon review and evaluation he finds that such variation and the required attendant changes in packaging, handling, and shipment procedures will provide protection at least equivalent to the above requirements.

(Sec. 312, 58 Stat. 880; 43 U.S.C. 216. Interpretation of applic. sec. 361, 58 Stat. 708; 43 U.S.C. 369a)

Dated:

[SEAL] JAMES M. HUNLEY,
Acting Surgeon General
Approved: August 7, 1964.

ANTHONY J. CELESZINSKI,
Secretary.

(P.R. Doc. 64-2234, Filed Aug. 13, 1964, 8 47 a.m.)

* See 20 P.R. 11419, August 7, 1964.

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