Federal Register
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Friday, May 4, 1990

Presidential Documents

Title 3—

The President

Proclamation 6126 of May 2, 1990

Be Kind to Animals and National Pet Week, 1990

By the President of the United States of America

A Proclamation

Animals and pets have been partners in our American way of life ever since our ancestors first came to these shores. On the frontier, horses and cattle were vital to plowing fields and to transporting people and goods. Dogs not only provided their masters with companionship, but also played a vital role in protecting farmers' and ranchers' livestock.

Today animals and pets continue to be valued by their owners—especially children and older Americans. By caring for pets, children acquire a sense of responsibility and gentleness. They learn that, to remain healthy, pets must have proper food, exercise, and adequate shelter. Many elderly men and women find both security and an answer to loneliness through their pets. For these Americans, and, indeed, for Americans of all ages, household pets and other domestic animals bring fun-filled hours of play and the quiet joy of loyal companionship.

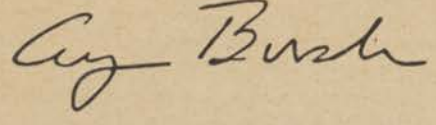
For Americans who are deaf, visually impaired, or otherwise physically disabled, specially trained animals not only serve as a source of companionship but can also provide the assistance needed to live and work with confidence and independence. These animals are integrated into many rehabilitation programs, as well. Every American benefits from use of specially trained animals in the work of law enforcement officers and customs officials.

This week, we acknowledge the many rewards of owning animals and pets, as well as our obligation to protect them against inhumane treatment. We also recognize the dedicated members of the veterinary profession and members of our Nation's animal protection societies for their efforts to promote public awareness of the need to provide domestic animals with proper food, shelter, and veterinary care.

The Congress, by Senate Joint Resolution 236, has designated the week of May 6 through May 12, 1990, as "Be Kind to Animals and National Pet Week" and has authorized and requested the President to issue a proclamation in observance of this week.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim the week of May 6 through May 12, 1990, as Be Kind to Animals and National Pet Week. I call upon the American people to observe this week with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this second day of May, in the year of our Lord nineteen hundred and ninety, and of the Independence of the United States of America the two hundred and fourteenth.



[FR Doc. 90-10628
Filed 5-3-90; 10:34 am]
Billing code 3195-01-M

Presidential Documents

Executive Order 12713 of May 1, 1990

Report Required by Section 502 of the Automotive Products Trade Act of 1965

By the authority vested in me as President by the Constitution and laws of the United States of America, including the Automotive Products Trade Act of 1965 (19 U.S.C. 2001 *et seq.*) ("Act"), and in order to provide for the submission to the Congress of the annual report required by section 502 of the Act (19 U.S.C. 2032), it is hereby ordered that authority for submission of the report is delegated to the Secretary of Commerce.

THE WHITE HOUSE,
May 1, 1990.

[FR Doc. 90-10592
Filed 5-2-90; 3:13 pm]
Billing code 3195-01-M

Rules and Regulations

Federal Register
Vol. 55, No. 87
Friday, May 4, 1990

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 89F-0148]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

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 2,2'-(2,5-thiophenediyl)bis(5-*tert*-butylbenzoxazole) as an optical brightener for polycarbonate resins complying with 21 CFR 177.1580. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective May 4, 1990; written objections and requests for a hearing by June 4, 1990.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 26, 1989 (54 FR 22813), FDA announced that a food additive petition (FAP 9B4142) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532-2188, proposing that § 178.3297 *Colorants for polymers* (21 CFR 178.3297) be amended to provide for the safe use of 2,2'-(2,5-thiophenediyl)bis(5-*tert*-butylbenzoxazole) as an optical brightener for polycarbonate resins complying with 21 CFR 177.1580.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that the regulations should be amended in § 178.3297 in the table of paragraph (e) by adding item "5." under the heading "Limitations" for 2,2'-(2,5-thiophenediyl)bis(5-*tert*-butylbenzoxazole) 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 21 CFR 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.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before June 4, 1990, file with the Dockets Management Branch (address above) written objections thereto. 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 shall be submitted and shall 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 178

Food additives, 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 part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.3297 is amended in the table of paragraph (e) by adding item "5." under the heading "Limitations" for the entry "2,2'-(2,5-Thiophenediyl)bis(5-*tert*-butylbenzoxazole) * * *" to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * * * *	
2,2'-(2,5-Thiophenediyl)-bis(5-*tert*-butylbenzoxazole) (CAS Reg. No. 7128-64-5).	* * *

Substances	Limitations
	5. At levels not to exceed 0.015 percent by weight of polycarbonate resins complying with § 177.1580 of this chapter. The finished polymer shall contact foods of the types identified in Table 1 of § 176.170(c) of this chapter, under categories, I, II, IV–B, VI–B, and VIII under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter.

* * * * *

Dated: April 25, 1990.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90–10345 Filed 5–3–90; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 310

[Docket No. 86N–0336]

Prescription Estrogen Drug Products; Patient Package Insert Requirement

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the requirements for patient package inserts for estrogen drug products. The revised requirements will help ensure that patient package inserts accurately reflect current information about this class of drug products.

EFFECTIVE DATE: September 4, 1990.

FOR FURTHER INFORMATION CONTACT: Adele S. Seifried, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8046.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 22, 1977 (42 FR 37636), FDA first required manufacturers and dispensers of estrogens to make information available to patients about the use of these products. The regulation adopted at that time required that estrogens be dispensed with a brief informational leaflet directed to the patient, describing the product's benefits and risks. The leaflet—now called a patient package insert—contained information about side effects associated with the use of estrogens and emphasized the importance of patients discussing the use of these drugs with their physicians. The leaflet noted that a booklet containing more information about the drug product was available from the patient's physician.

In the **Federal Register** of October 9, 1987 (52 FR 37802), FDA proposed to revise the requirements for patient package inserts for estrogen drug products. These proposed changes were intended (1) to update the technical information in the patient package insert about the benefits and risks of estrogen drug use, and (2) to simplify the content and format of the patient package insert to make the insert more readable and understandable. The proposal was also designed to ensure that the insert could be revised in a more timely fashion to reflect current information about this class of drug products. FDA also proposed to establish more flexible distribution requirements for estrogen drug products and to eliminate current requirements with respect to printing specifications for the patient package insert. After careful consideration of the comments received by the agency, this rule finalizes most of the proposed changes, with a few exceptions.

II. Summary of Comments and the Agency's Responses

Interested persons were given 90 days to submit comments on the proposed rule. The agency received five comments. These are summarized below with the agency's responses.

1. *Printing specifications.* The agency proposed several changes to simplify the patient package insert and to allow manufacturers and other labelers greater flexibility in developing and distributing patient package inserts. In particular, to enhance manufacturers flexibility in preparing patient package inserts, FDA proposed to eliminate current requirements with respect to printing specifications for the patient package inserts. One comment urged the agency to retain the printing specifications, arguing that many women who require estrogen medication are older and have declining eyesight.

Except in the regulations imposing patient package inserts for specific drug products, FDA has not in the past established printing specifications for prescription drug labeling. The agency has found that its routine review of final printed labeling for drugs subject to premarketing clearance, and its other compliance activities, have been adequate to ensure that drug labeling can be read by its intended audiences. The agency now believes that this kind of monitoring of labeling practices obviates the need to mandate printing specifications for patient labeling.

2. *Distribution of the patient package insert.* The proposal would have relaxed the current requirement that a patient package insert physically accompany every package throughout distribution, and would have allowed alternate distribution methods. Two comments urged the agency to retain the current provision that requires that the patient package insert be included in or attached directly to each dispensed package. The comments argued that this is the best method of assuring distribution of patient package inserts to all consumers.

The agency has carefully considered these comments. The agency agrees that the proposed change in distribution requirements may increase the likelihood that some patients may not receive the patient package insert. The agency also agrees that discontinuing the requirement that the patient package insert be included in or with each dispensed package will increase the likelihood that patients will not receive the required information. Moreover, the agency notes that no comments expressed support for the proposed distribution scheme. For these reasons, the agency concludes that the current provision requiring that the patient package insert be included in or with each package of the drug product should be retained.

3. *Posting of signs to inform consumers of available information.* One comment urged the agency to require the posting of signs in every pharmacy, in physician's offices where sample medications are distributed, in ambulatory care centers, and in hospitals informing patients of their right to request written medication information on any prescription.

The agency shares the concern that patients be adequately informed about their prescription medications. In 1983, in conjunction with the National Council of Patient Information and Education (NCPIE), the agency launched a campaign to encourage patients to communicate with their doctors and pharmacists about their drug prescriptions. The "Get the Answers" campaign, which was disseminated through news releases, advice columns, and drug leaflet systems, urged patients to ask their health professionals questions about their prescriptions. In 1984, FDA conducted a successful "Ask the Doctor about Prescription Drugs" day in cooperation with the American Academy of Family Physicians and a "Call for Action." Also in 1984, NCPIE