would allow us to determine whether an organism could be safely employed for the biological control of weeds. Through our previous experience with determining the safety of potential biological control organisms of weeds, we have developed several questions that speak to the primary factor that must be considered in assessing such releases, i.e., host specificity. Those questions are:

- Does the organism feed upon, infect, or suppress only the target plant species or a few closely related species?
- If an arthropod, does the organism deposit eggs on plant species besides the target? If so, how closely are these plant species related to the target? Similarly, if the organism is a plant pathogen, can its spores or other propagules germinate and penetrate the tissues of plants other than the target?
- If the organism deposits eggs on plant species other than the target, do those eggs hatch and can the resulting immature stages significantly feed on them and complete their development? For plant pathogens, does penetration of the plant tissues lead to disease symptoms or signs in the plant?
- If the organism is an arthropod, are its immature stages capable of completing development on plants other than the target, and are the resulting adults fertile? Similarly, if the organism is a plant pathogen, does infection of nontarget plants result in the subsequent production of viable spores or other infective units?
- Does the probable ecological range (especially those related to tolerances for physical environmental parameters, especially temperature and humidity) of the organism overlap the distribution of native plant species that are related to the target in the United States and that are attacked in laboratory tests?
- Is the organism closely related to other species or strains that exhibit narrow or broad host specificities?
- Can the organism feed upon, attack, infect, or otherwise adversely impact endangered or threatened plant or animal species in the United States?

We are seeking your input on the appropriateness of these questions for assessing the risks of releasing organisms with plant pest characteristics for the biological control of weeds. What other considerations might be appropriate for such an assessment? Should any special requirements be imposed on organisms proposed for release on islands such as Puerto Rico or the State of Hawaii? Should APHIS require applicants to submit post-release monitoring data regarding possible attacks on nontarget plant species?

Public Hearing

APHIS will host a public hearing to provide interested persons a full opportunity to present oral presentations of data, views, arguments, and questions regarding this advance notice of proposed rulemaking. The hearing will be held on November 7, 1996, at the USDA Center at Riverside, 4700 River Road, Riverdale, MD.

A representative of APHIS will preside at the public hearing. Any interested person may appear and be heard in person, by attorney, or by other representative. Persons who wish to speak at the public hearing will be asked to sign in, listing their names and organizations.

The public hearing will begin at 10 a.m. local time and is scheduled to end at 5 p.m. local time. However, the hearing may be terminated at any time after it begins if all persons desiring to speak have been heard. We ask that anyone who reads a statement provide two copies to the presiding officer at the hearing. If the number of speakers at the hearing warrants it, the presiding officer may limit the time for each presentation so that everyone wishing to speak has the opportunity.

We welcome all comments on the scope, approach, criteria, and issues outlined above and encourage the submission of ideas on any associated topics or other suggestions for the evaluation of plant pest risk and the improvement of the evaluation and permitting process. APHIS will consider all comments and recommendations in developing any revisions to the current FPPA regulations and will initiate rulemaking for any changes deemed appropriate.

Authority: 7 U.S.C. 149, 150bb, 150dd, 150ee, 150ff, 154, 159, 160, 162, and 2260; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(c).

Done in Washington, DC, this 24th day of September 1996.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–24847 Filed 9–26–96; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 95P–0337/CP1]

Food Labeling: Saccharin and Its Salts; Retail Establishment Notice; Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revoke the food labeling regulation that prescribes conditions for the display by a retail establishment of a notice concerning the sale of products containing saccharin and its salts. This action is being taken in response to the enactment of Pub. L. 104–124, which amended the Federal Food, Drug, and Cosmetic Act (the act), and a citizen petition submitted by the Calorie Control Council. This action is intended to reduce the burden on small businesses.

DATES: Comments by December 11, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS–151), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

SUPPLEMENTARY INFORMATION: FDA is proposing to amend its food labeling regulations by revoking § 101.11 *Saccharin and its salts; retail establishment notice* (21 CFR 101.11). In the Federal Register of March 3, 1978 (43 FR 8793), FDA adopted § 101.11 to implement a provision of the Saccharin Study and Labeling Act (Pub. L. 95–203) (hereinafter referred to as the SSLA). Among other things, the SSLA amended the act by adding section 403(p) (21 U.S.C. 343(p)), which provided that a food would be misbranded if it contained saccharin and was offered for sale, but not for immediate consumption, at a retail establishment unless the retail establishment displayed specific information relative to saccharin and its salts.

On October 11, 1995, FDA received a citizen petition from the Calorie Control Council requesting that the agency revoke § 101.11. The petition claimed

that: (1) ''[T]he language of the notice is outdated and appears to have been intended for a labeling transition that took place during 1977–1978,'' (2) ''specific requirements of the regulation are outdated,'' and (3) ''the regulation is one that should be deleted per President Clinton's request for a list of regulations that the agency plans to eliminate.''

Subsequently, on April 1, 1996, the President signed into law Pub. L. 104–124 to amend the act by repealing section 403(p) of the act. In discussing the provisions of H. R. 1787, which was enacted as Pub. L. 104–124, the House report reflected on the intent of the SSLA provision for a store placard and the intent of Pub. L. 104–124 that the placard no longer be required:

> The redundant store notice warning requirement was included as a stop-gap measure to provide the warning prior to the time that warning labels would begin to appear on foods containing saccharin. Now that warning labels appear on all products, this requirement is no longer necessary. Eliminating the store warning notice will reduce a burden on retail establishments including ''mom and pop'' grocery stores, neighborhood supermarkets, pharmacies, and convenience stores.

H. Rept. 104–386, page 2 (December 6, 1995).

In view of the revocation of section 403(p) of the act by Pub. L. 104–124 and the fact that section 403(o) of the act, which was also added to the act by the SSLA, requires that all food products containing saccharin include on their labeling a warning statement (see Statement of final guidelines for labeling of food products containing saccharin (42 FR 62209, December 9, 1977)), the agency tentatively finds that § 101.11 is no longer necessary and should be revoked. This action responds to the request in the Calorie Control Council's citizen petition. This action is also consistent with the Administration's ''Reinventing Government'' initiative which seeks to ease burdens on regulated industry and consumers.

FDA has determined that this proposed rule is not a significant regulatory action for the purposes of Executive Order 12866. This proposed rule is expected to reduce the burden on small businesses. Therefore, the agency certifies that this proposed rule will not have a significant adverse impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*)

The agency has determined under 21 CFR 25.24(a)(11) 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.

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is intended to minimize the reporting and recordkeeping burden on the regulated community, as well as to minimize the cost of Federal information collection and dissemination. In general, the Paperwork Reduction Act of 1995 requires that information requests and recordkeeping requirements affecting 10 or more non-Federal respondents be approved by the Office of Management and Budget. Because this proposed rule would remove an existing regulation and would not establish or modify any information or recordkeeping requirements, it is not subject to the requirements of the Paperwork Reduction Act of 1995.

Interested persons may, on or before December 11, 1996 submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

> Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

§ 101.11 [Removed]

2. Section 101.11 *Saccharin and its salts; retail establishment notice* is removed from subpart A.

Dated: September 19, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–24754 Filed 9–26–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 96N–0240]

Food Labeling; Dietary Supplement; Nutritional Support Statement; Notification Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to establish the procedure by which manufacturers, packers, and distributors of dietary supplements who are marketing a dietary supplement product that bears on its label or in its labeling one of the types of statements provided for in the Federal Food, Drug, and Cosmetic Act (the act) are to notify FDA of that fact. FDA is issuing this proposal in response to the Dietary Supplement Health and Education Act of 1994 (the DSHEA) and to inquiries from the dietary supplement industry.

DATES: Written comments by December 26, 1996.

ADDRESSES: Written comments may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5372.

SUPPLEMENTARY INFORMATION:

I. Background

On October 25, 1994, the DSHEA (Pub. L. 103–417) was signed into law. The DSHEA, among other things, amended the act by adding section 201(ff) (21 U.S.C. 321(ff)), which defines a ''dietary supplement,'' by adding section 403(r)(6) (21 U.S.C. 343(r)(6)), which provides for the use of certain types of statements on the labels and in the labeling of dietary supplements, and by amending section 201(g)(1), which defines ''drug,'' to state: ''A food, dietary ingredient, or dietary supplement for which a truthful and nonmisleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.''

Section 403(r)(6) states that a statement for a dietary supplement may be made if:

> [T]he statement claims a benefit related to a classical nutrient deficiency disease and