conviction, or other legal process, the port director must have probable cause to believe the proscribed acts occurred;

(3) The carrier-participant or a designated driver allows an unauthorized person or entity to use its LBCIP certificate or other approved form of identification;

(4) The carrier-participant or a designated driver misuses authorized conveyances;

(5) The carrier-participant or a designated driver refuses or otherwise fails to follow any proper order of a Customs officer or any Customs order, rule, or regulation relative to continued participation in the LBCIP;

(6) The carrier-participant or a designated driver fails to operate in accordance with the terms of the written agreement; or

(7) Continuation of LBCIP privileges would endanger the revenue or security of the Customs area in the judgment of the port director.

(b) *Notice.* When a decision revoking participation has been made, the port director shall notify the carrier-participant, and, where appropriate, the individual designated driver(s), of the decision in writing. The notice of revocation shall clearly state the reason(s) for revocation and recite the applicant's/driver's appeal rights under paragraph (c) of this section.

(c) *Appeal.* An LBCIP participant who receives a notice of revocation and who wishes to appeal the decision shall file a written appeal with the Assistant Commissioner, Office of Field Operations, U.S. Customs Service, Washington, D.C. 20229, within 10 calendar days of receipt of the notice. The appeal shall be filed in duplicate and shall set forth the participant's responses to the grounds specified by the port director in the notice. Within 30 working days of receipt of the appeal, the Assistant Commissioner, or his designee, shall make a determination regarding the appeal and notify the applicant in writing.

PART 142—ENTRY PROCESS

1. The authority citation for part 142 continues to read as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1624.

2. Section 142.41 is amended by adding a sentence at the end to read as follows:

§ 142.41 Line release.

* * * * *

At certain high-risk locations along the land borders of the United States (the locations to be published in the **Federal Register**), which are approved by Customs for handling Line Release, the use of Line Release may be denied by Customs unless the imported merchandise is transported by carriers and drivers that participate in the Land Border Carrier Initiative Program (see, subpart H of part 123 of this chapter).

§ 142.47 [Amended]

3. In § 142.47, the first sentence of paragraph (b) is amended by removing the words ''because of an examination'' and adding, in their place, the words ''for the following reasons: because of an examination, because a carrier transporting the Line Release merchandise is not a participant in the Land Border Carrier Initiative Program (LBCIP), or because a driver or conveyance is not authorized in accordance with the LBCIP''.

Samuel H. Banks,

Acting Commissioner of Customs.

Approved: August 7, 1997.

Dennis M. O'Connell,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 97–33854 Filed 12–29–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 330, and 358

[Docket No. 96N–0420]

Over-The-Counter Human Drugs; Proposed Labeling Requirements; Notice of Availability of Study Data and Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period on specific data.

SUMMARY: The Food and Drug Administration (FDA) is reopening to February 13, 1998 the comment period on specific data related to the February 27, 1997, proposed rule to establish a standardized format for the labeling of over-the-counter (OTC) drug products (62 FR 9024). As part of that rulemaking proceeding, the agency collected data under a study entitled ''Over-the-Counter (OTC) Label Format Preference, Study B.'' (Study B). This document announces the availability of the data and frequency tabulations that summarize the Study B data and reopens the comment period for the OTC rulemaking proceeding to allow an opportunity for comment on Study B.

DATES: Submit written comments on Study B by February 13, 1998.

ADDRESSES: Submit written comments on the information collected in Study B to the Dockets Management Branch (HFA–305), ATTN: Study B, OTC Drug Labeling Data Collection, Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kathryn J. Aikin, Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications (HFD–40), 5600 Fishers Lane, Rockville, MD, 20857, 301–827–2828, Aikink@cder.fda.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 27, 1997 (62 FR 9024), FDA published a proposed rule intended to enable consumers to read and understand OTC drug product labeling and to more effectively apply the information in the labeling to the safe and effective use of such products. An important element of FDA's proposed rule is a standardized labeling format for OTC drug products.

After issuing the proposed rule, FDA published in the **Federal Register** a notice under the Paperwork Reduction Act of 1995 announcing the agency's intention to conduct four studies relating to OTC drug products (62 FR 28482, May 23, 1997). The agency intends at this time to use two of the studies (''Evaluation of Proposed Over-the-Counter (OTC) Label Formats, Study A,'' and ''Over-the-Counter (OTC) Label Format Preference, Study B'') in deliberations on developing a standardized, easy to read and easy to understand, labeling format for OTC drug products (see 62 FR 9024). The data and frequency tabulations for one of these studies, Study B, are now available.

In Study B, consumers were invited to view examples and variations of current OTC label designs. Respondents were asked to indicate their preference for various designs and to evaluate labeling terminology and graphics to help the agency understand how consumers interpret various ways of communicating drug safety and drug effectiveness information. The agency is now seeking comments on the data developed under Study B, including the opinions of the respondents on the various labeling format elements used in the Study. The comments on Study B will be included in the agency's deliberations on developing a final, standardized OTC labeling format regulation.

After the results for Study A are tabulated, the agency will publish a notice in the **Federal Register** announcing when the data and tabulations are available for viewing.

Interested persons may, on or before February 13, 1998, submit written comments on the data developed under Study B to the Dockets Management Branch (address above). 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 and labeled ''ATTN: Study B, OTC Drug Labeling Data Collection.'' The data, frequency tabulations, and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic format of the data are available on the internet at: www.fda.gov/CDER/ or can be obtained in electronic form from the Dockets Management Branch at the address listed above.

Dated: December 19, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–33803 Filed 12–29–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 91N–384H and 96P–0500]

RIN 0910–AA19

Food Labeling: Nutrient Content Claims, Definition of Term: Healthy

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is considering whether to institute rulemaking to reevaluate and possibly amend certain provisions of the nutrient content claims regulations pertaining to the use of the term ''healthy.'' This action is in response to a citizen petition from ConAgra, Inc., to amend the definition of this term. The petitioner has raised important issues regarding both the technological feasibility of reductions in sodium levels in foods that currently meet FDA's definition for the term ''healthy'' and the safety of at least some of these foods if there are reductions in their sodium levels. The agency is requesting that data be submitted relative to these issues. In addition, FDA is responding to comments that it received in response to a stay of certain provisions pertaining to the use of the term ''healthy.''

DATES: Written comments by March 16, 1998.

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: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5483.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 10, 1994 (59 FR 24232), FDA published a final rule to establish a definition of the term ''healthy'' under section 403(r) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)). In that final rule, FDA stated that the fundamental purpose of a ''healthy'' claim is to highlight those foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to current dietary guidelines (59 FR 24232 at 24233). In its consideration of comments relative to the proposed qualifying level of sodium to be incorporated into the definition of the term ''healthy,'' the agency rejected comments that suggested that the food should meet the requirements for ''low sodium'' (59 FR 24232 at 24239). The agency stated that such a definition was too restrictive, and that many foods that would otherwise meet the definition of ''healthy'' would be disqualified by a ''low sodium'' requirement. The agency stated that for the claim to be useful, foods that are able to bear the term should be of a sufficient number and variety to help consumers achieve a total diet that is consistent with current dietary recommendations (59 FR 24232 at 24239).

The agency explained that sodium plays an important role in consumer acceptance of a product, and that many products that qualify to bear a claim for ''healthy'' may lose their appeal to consumers because of an unacceptable flavor profile if, in addition to being low in fat and saturated fat, the foods were low in sodium. FDA stated that, if consumers abandon products or add salt to taste at the table, foods bearing the term would lose their usefulness in assisting consumers to achieve dietary recommendations with respect to sodium intake (59 FR 24232 at 24239).

Based on the comments to the proposed rule for ''healthy'' relative to specific sodium levels, the agency adopted qualifying criteria of 360 milligrams (mg) of sodium per reference amount customarily consumed (RACC) in individual foods and 480 mg sodium per RACC in main dish and meal products (59 FR 24232 at 24240). In addition, the agency established a transition period to allow time for industry to reformulate products to meet the new qualifying sodium levels. The agency determined that levels of 480 mg of sodium in individual foods, single ingredient seafood, and game meat, and of 600 mg of sodium in main dishes and meal products, were appropriate levels during the transition period, but that after January 1, 1998 (essentially 3-1/2 years from the date of publication of the final rule), these foods would have to meet the lower sodium qualifying levels to bear the claim ''healthy'' (59 FR 24232 at 24241 and 24245 and see § 101.65(d)(2)(ii), (d)(3)(ii), and (d)(4)(ii) (21 CFR 101.65(d)(2)(ii), (d)(3)(ii), and (d)(4)(ii))).

On December 13, 1996, FDA received a petition from ConAgra, Inc. (the petitioner), 888 17th St. NW., suite 300, Washington, DC 20006, requesting that § 101.65(d) be amended to ''eliminate the sliding scale sodium requirement for foods labeled 'healthy' by eliminating the entire second tier levels of 360 mg sodium for individual foods and 480 mg sodium for meals and main dishes'' (Docket 96P–0500, CP–1, p. 1). Alternatively, the petitioner requested that the effective date of January 1, 1998, in § 101.65(d)(2) through (d)(4) be delayed until such time as food technology catches up with FDA's goals to reduce the sodium content of foods, and until there is a better understanding of the relationship between sodium and hypertension.

The agency was persuaded by the petition that it is in the public interest to stay the effect of the lower standards for sodium in the definition of ''healthy'' in § 101.65 while the agency endeavors to resolve the issues raised by the petition. Therefore, in the **Federal Register** of April 1, 1997 (62 FR 15390), FDA published a final rule that stayed, until January 1, 2000, the effective date of January 1, 1998, in § 101.65(d)(2)(ii) and (d)(4)(ii) for when foods must achieve the lower sodium levels (the ''second tier levels'') to qualify to bear the term ''healthy.'' The agency said that it was issuing the stay to allow itself time to reevaluate the standard, and to evaluate the data contained in the petition and any additional data that it may receive; to conduct any subsequent notice-and-comment rulemaking that it finds is necessary; and to allow ample time for implementation of the rule or of any changes in the rule that may result from the agency's reevaluation.