

(A) An estimate of the biologic variability in the availability of the substance in humans and in the relationship between the amount of the substance ingested and the rate of absorption (i.e., dose-response);

(B) A statement of the relevance, and limit to relevance to the human, of any animal model used to estimate human digestion and absorption of the substance; and

(C) For any clinical studies that are relied on to demonstrate reduced absorption or digestion, information on the characteristics of the subjects studied and the manner in which they are representative of the population for whom the substance is intended. For example:

(1) An accounting of subjects enrolled in the study including those who did not complete the study, reasons for any noncompletion, and an assessment of the effect that noncompletion of subjects had on the results of the study; and

(2) A description of any adverse events that occurred during the study, and a comparison of the frequency and type of effects as a function of the feeding of the substance;

(ii) Information about foods or diets that may affect the digestibility coefficient, such as:

(A) Interactions of the substance with other components of foods or the diet that could significantly affect the digestibility coefficient;

(B) Steps in processing of the types of foods expected to contain the fat substitute that could affect the digestibility coefficient;

(C) The amount of the substance used in feeding studies, the relationship of that amount to expected levels of intake, and the dose-response relationship between the amount of the substance and the digestibility coefficient; and

(D) The duration of feeding studies and changes in the digestibility coefficient with continued exposure;

(6) A certification that all data of which the firm is aware that pertain to the digestibility of the fat substitute have been submitted, and that any new data will be promptly submitted as it becomes available for as long as the ingredient is marketed; and

(7) Such notification shall be submitted to the Office of Food Labeling (HFS-150), Food and Drug Administration, 200 C St., SW., Washington, DC 20204.

(d) *FDA review.* Upon receipt, FDA will notify the submitting firm that it has received the notification and will commence its review. If firms do not receive written objections from FDA within 120 days of FDA's receipt of the notification, nutrient content claims

based on the digestibility coefficient submitted may be used.

(e) *Nutrition labeling.* When a claim is made for fat or saturated fat under this section, the nutrition label shall declare the amount of available fat or saturated fat in accordance with § 101.9(d)(15).

(f) *Misbranding.* Any food product containing ingredients that are covered under paragraph (a) of this section that bears a claim based on available levels of fat for which supporting data have not been provided to FDA in accordance with this section or to which FDA has objected in response to the notification filed in accordance with paragraph (c) of this section will be deemed to be misbranded under section 403(a) and (r)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

Dated: December 11, 1996.
William B. Schultz,
Deputy Commissioner for Policy
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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-209672-93]

RIN 1545-AS16

Credit for Employer Social Security Taxes Paid on Employee Tips

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Withdrawal of notice of proposed rulemaking.

SUMMARY: This document withdraws the notice of proposed rulemaking relating to the credit for employer FICA taxes paid with respect to certain tips received by employees of food or beverage establishments. The proposed regulations were published in the Federal Register on December 23, 1993. Changes to the law made by the Small Business Job Protection Act of 1996 have made these proposed regulations obsolete.

FOR FURTHER INFORMATION CONTACT: Jean M. Casey at (202) 622-6060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On December 23, 1993, the IRS issued proposed regulations (EE-71-93) (58 FR 68091) under section 45B of the Internal Revenue Code relating to the credit for employer FICA taxes paid with respect to certain tips received by employees of

food or beverage establishments. Amendments made by section 1112(a) of the Small Business Job Protection Act of 1996 (Public Law 104-188) render the proposed regulations obsolete. Therefore, proposed regulation § 1.45B-1 is being withdrawn.

On December 23, 1993, the IRS also published temporary regulations (TD 8503) (58 FR 68033) under section 45B of the Code. These temporary regulations are being removed in a separate document.

List of Subjects in 26 CFR Part 1

Income taxes, Penalties, Reporting and recordkeeping requirements.

Withdrawal of Notice of Proposed Rulemaking

Accordingly, under the authority of 26 U.S.C. 7805, the notice of proposed rulemaking that was published in the Federal Register on December 23, 1993 (58 FR 68091) is withdrawn.

Margaret Milner Richardson,
Commissioner of Internal Revenue.
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Financial Crimes Enforcement Network Proposed Amendments to the Bank Secrecy Act Regulations Regarding Reporting and Recordkeeping by Card Clubs

31 CFR Part 103

RIN 1506-AA18

AGENCY: Financial Crimes Enforcement Network, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Financial Crimes Enforcement Network ("FinCEN") is proposing to amend the regulations implementing the statute generally referred to as the Bank Secrecy Act to include certain gaming establishments, commonly called "card clubs," "card rooms," "gaming clubs," or "gaming rooms" within the definition of financial institution subject to those regulations.

DATES: Written comments must be received on or before March 20, 1997.

ADDRESSES: Written comments should be submitted to: Office of Regulatory Policy and Enforcement, Financial Crimes Enforcement Network, Department of the Treasury, 2070 Chain Bridge Road, Vienna, Virginia 22182, Attention: NPRM—Card Clubs.

SUBMISSION OF COMMENTS: Comments on all aspects of the proposed regulation are welcome and will be considered if submitted in writing prior to March 20,