The document invited the public to comment on the proposal. Comments on the proposed rule were requested on or before March 27, 2000.

Customs has received a request to extend the comment period for an additional 30 days from the Alliance of Automobile Manufacturers to enable the organization to coordinate its comment with its member companies.

Customs has determined to grant the request for the extension. Accordingly, the period of time for the submission of comments is being extended 30 days. Comments are now due on or before April 26, 2000.

Dated: March 29, 2000.

Stuart P. Seidel,

Assistant Commissioner, Office of Regulations and Rulings.

[FR Doc. 00–8141 Filed 3–31–00; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 111

[Docket No. 95N–0304]

Dietary Supplements Containing Ephedrine Alkaloids; Withdrawal in Part

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal in part.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is withdrawing certain provisions of a proposed rule that published in the **Federal Register** of June 4, 1997 (62 FR 30678), relating to dietary supplements containing ephedrine alkaloids. FDA is taking this action because of concerns regarding the agency's basis for proposing a certain dietary ingredient level and a duration of use limit for these products. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of new adverse event reports and related information associated with these products and its plans to participate in a public forum to discuss this new information at some future date. In addition, FDA is announcing elsewhere in this issue of the **Federal Register** the availability of additional documentation associated with certain adverse events referenced in the 1997 proposed rule.

DATES: The proposed rule that published on June 4, 1997 (62 FR 30678) is withdrawn in part for § 111.100(a), (b), (c), (e), and (f) as of April 3, 2000.

ADDRESSES: Copies of the proposed rule and related comments are available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marquita B. Steadman, Center for Food Safety and Applied Nutrition (HFS–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–827–6733.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 4, 1997 (62 FR 30678), FDA published a proposed rule (hereinafter referred to as the ''ephedrine alkaloids proposal'') to establish that a dietary supplement is adulterated if it contains 8 milligrams (mg) or more of ephedrine alkaloids per serving, or if its labeling suggests or recommends conditions of use that would result in an intake of 8 mg or more within a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids (hereinafter referred to as ''dosing level'' or ''dietary ingredient level''), and to require that the label of such supplement state that the product is not to be used for more than 7 days (hereinafter referred to as ''duration of use limit''). The agency also proposed to prohibit the use of ephedrine alkaloids in dietary supplements with ingredients, or with ingredients that contain substances, that have a known stimulant effect, such as caffeine, which may interact with ephedrine alkaloids; and to prohibit labeling claims, such as weight loss or body building, that require long-term intake to achieve the purported effect. In addition, the agency proposed to require a statement to accompany claims that encourage short-term excessive intake to enhance a purported effect, such as an increase in energy, that taking more than the recommended serving may result in serious adverse health effects; and to require specific warning statements to appear on product labels.

The agency proposed these actions in response to reports of serious illnesses and injuries, including a number of deaths, associated with the use of dietary supplement products containing ephedrine alkaloids and the agency's investigations and assessment of these illnesses and injuries. This action was also supported by many of the recommendations made during the October 1995 meeting of an ad hoc Working Group of the FDA Advisory Committee (Working Group) and the August 1996 meeting of the Food Advisory Committee (FAC) and the Working Group concerning the potential public health problems associated with the use of dietary supplements containing ephedrine alkaloids and the recommended steps FDA should take to address the serious health concerns associated with their use (see Refs. 25 and 27 of the ephedrine alkaloids proposal (Docket No. 95N–0304)).

The comment period for the June 4, 1997 (62 FR 30678), proposed rule closed on August 18, 1997. In a notice in the **Federal Register** of August 20, 1997 (62 FR 44247), FDA announced its intent to reopen the comment period after the agency corrected a number of inadvertent omissions in the administrative record. Subsequently on September 18, 1997 (62 FR 48968), the agency reopened the comment period for an additional 75 days until December 2, 1997.

The agency received approximately 350 letters regarding the use of ephedrine alkaloid-containing dietary supplements prior to publication of the ephedrine alkaloids proposal. These comments have been considered by the agency along with those commenting in response to the proposal. The agency received approximately 14,775 comments on the ephedrine alkaloids proposal. Individual consumers who use ephedrine alkaloid-containing dietary supplements and independent distributors of these products submitted most of the comments. Other comments were received from persons who had, or who knew persons who had, suffered adverse events or who were reporting adverse events associated with the use of an ephedrine alkaloid-containing dietary supplement. The remaining comments included those submitted by medical professionals, scientists, a scientific association, State and local health departments, medical associations, government agencies, dietary supplement manufacturers, Chinese medicine practitioners and associations, dietary supplement industry trade associations, public health associations, and consumer groups.

The House Committee on Science requested that the Government Accounting Office (GAO) examine the scientific bases for the ephedrine alkaloids proposal and the agency's adherence to the regulatory flexibility analysis requirements for Federal rulemaking. On August 4, 1999, GAO released its report entitled ''Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids.'' A copy of this

report is available in Docket No. 95N–0304.

Generally, GAO concluded that FDA was justified in determining that the number of adverse event reports relating to dietary supplements containing ephedrine alkaloids warranted the agency's attention and consideration of steps to address safety issues. However, GAO expressed concerns about the use of the reported adverse events in supporting the proposed dosing level and duration of use limit, and concluded that the agency needed additional evidence to support these restrictions.

GAO also concluded that FDA's economic analysis contained the basic elements expected in a Federal agency's cost-benefit analysis, and the ephedrine alkaloids proposal complied with regulatory flexibility analysis requirements under the Regulatory Flexibility Act. GAO noted, however, that FDA's cost-benefit analysis was not always transparent regarding why certain key assumptions were made, the degree of uncertainty involved in those assumptions, or the effect that alternative assumptions would have had on the agency's estimates of the costs and benefits of the proposed action.

GAO recommended that FDA ''provide stronger evidence on the relationship between the intake of dietary supplements containing ephedrine alkaloids and the occurrence of adverse reactions that support the proposed dosing level and duration of use limits.'' In addition, GAO recommended that FDA improve the transparency of its cost-benefit analysis in its final rulemaking.

In light of GAO's conclusions, comments from others on the ephedrine alkaloids proposal, and having further considered issues related to the proposed dietary ingredient level and the duration of use limit, FDA believes that these aspects of its proposed approach to regulating these products should be reassessed. Whether there are appropriate alternative approaches to these aspects of the proposal for regulating dietary supplements containing ephedrine alkaloids will require evaluation of additional information not available to the agency when it issued the proposal. Accordingly, FDA is withdrawing the provisions of the ephedrine alkaloids proposal relating to the dietary ingredient level and duration of use limit for these products. This action will allow FDA to reconsider, with public input, whether any dietary ingredient level or duration of use limit for these products is appropriate or whether alternative measures should be considered. The withdrawn provisions are described briefly below.

II. Withdrawn Provisions of the Ephedrine Alkaloids Proposal

A. Dietary Ingredient Limit for Ephedrine Alkaloids: Per Serving Basis (§ 111.100(a)(1)) and Frequency and Per Total Daily Intake Basis (§ 111.100(b))

As stated above, the agency tentatively concluded in the ephedrine alkaloids proposal that a dietary supplement is adulterated if it contains 8 mg) or more of ephedrine alkaloids per serving (§ 111.100(a)(1)), or if the labeling suggests or recommends conditions of use that would result in an intake of 8 mg or more within a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids (§ 111.100(b)). Having reconsidered the basis for these limits, including comments on that basis by GAO and others to the proposal, FDA believes that it should consider additional information not available to the agency when it issued the ephedrine alkaloids proposal to determine whether a dietary ingredient limit, or some alternative approach, would be appropriate to regulate these dietary ingredients. Therefore, FDA is withdrawing these provisions of the ephedrine alkaloids proposal.

FDA continues to be concerned about the potential risk for individuals who are particularly sensitive to the effects of ephedrine alkaloids, or whose sensitivity or likelihood for adverse effects may be increased through chronic use of these products or other means (e.g., physical exercise). FDA expressed this concern in the proposal, and noted that many members of the FAC agreed.

B. Proposed Compliance Procedures (§ 111.100(a)(2))

In the ephedrine alkaloids proposal, FDA stated that it would use a high performance liquid chromatography method as specified in Laboratory Information Bulletin No. 4053 to determine the level of ephedrine alkaloids in a dietary supplement. Without a requirement that would establish an unacceptable dietary ingredient level for dietary supplements containing ephedrine alkaloids, this provision, alone, is no longer necessary. Accordingly, the agency has determined that this provision should also be withdrawn.

C. Proposed Limitations on Duration of Use (§ 111.100(c))

FDA proposed in § 111.100(c) to require that the label of dietary supplements that contain ephedrine alkaloids state ''Do not use this product for more than 7 days.'' FDA intended to require this provision in conjunction with the 8 mg per serving dietary ingredient limit proposed in § 111.100(a)(1). FDA noted in the ephedrine alkaloids proposal that concern about serious adverse events with the long-term use of ephedrine alkaloids led several members of the Working Group (see Ref. 27 of the ephedrine alkaloids proposal) and of the FAC (see Ref. 25 of the ephedrine alkaloids proposal (Docket No. 95N–0304)) to recommend that, in conjunction with a per serving dietary ingredient limit, FDA require a statement on the label of ephedrine alkaloid-containing dietary supplements to warn consumers not to use the product for a period longer than 7 days. FDA also cited evidence from the scientific literature about the adverse effects of long-term use of ephedrine alkaloids (62 FR 30678 at 30695).

FDA remains concerned with the long-term use of such products and the potential adverse effects such use has in combination with the use of other ingredients that have a stimulant effect. However, having reconsidered the basis for the proposed duration of use limit, including the comments on that basis by GAO and others to the proposal, FDA believes that it should consider additional information not available to the agency when it issued the ephedrine alkaloids proposal to determine whether any duration of use limit, or some alternative approach, is appropriate to regulate these products. In addition, the agency is also withdrawing the proposed 8-mg dietary ingredient limit. Therefore, the agency has determined that the proposed labeling requirement concerning duration of use should also be withdrawn.

D. Prohibition on Claims (§ 111.100(e) and (f))

FDA stated in the proposal that restrictions on claims are necessary to maintain the integrity of the limit on the level of ephedrine alkaloids in dietary supplements that it proposed and of the other proposed restrictions on the conditions of use of these dietary supplements. For example, because safe and significant weight loss and body building cannot be achieved in a 7-day period, FDA tentatively concluded that claims that promote these uses promote long-term use of ephedrine alkaloid-containing dietary supplements, which have been associated with serious adverse events. For this reason, FDA tentatively concluded that any claims that promote long-term use of ephedrine

alkaloid dietary supplements, such as those for weight loss and body building, promote conditions of use that present a significant and unreasonable risk of illness and injury. Consequently, FDA proposed in § 111.100(e) to require that no dietary supplement that contains ephedrine alkaloids may purport to be, or be represented as, either expressly or implicitly, for use for long-term effects, such as weight loss or body building.

Similarly, many claims found on the labels of, or in the labeling for, ephedrine alkaloid-containing dietary supplements, including increased energy, increased mental concentration, and enhanced well-being, encourage the consumer to take more of the product than is indicated on the label to achieve more of the purported effect. Consequently, FDA tentatively concluded that claims that promote excessive consumption are inconsistent with the dietary ingredient limit for these products. Accordingly, FDA proposed in § 111.100(f)(1) that the label or labeling for dietary supplements that contain ephedrine alkaloids that purport to be or are represented, either expressly or implicitly, to be used for short-term effects, such as increased energy, increased mental concentration, or enhanced well-being, must state ''Taking more than the recommended serving may cause heart attack, stroke, seizure or death.'' FDA proposed in § 111.100(f)(2) certain requirements on the size, type, and placement of this statement on the label. Because FDA is withdrawing the proposed dietary ingredient limit and duration of use limit, FDA has determined that the proposed provisions in § 11.100(e) and (f) should also be withdrawn. FDA believes that it should consider additional information not available to the agency when it issued the ephedrine alkaloids proposal before finally determining whether such provisions with respect to claims, or some alternative approach, is appropriate to regulate these products. Nonetheless, FDA remains concerned that adverse effects are associated with long-term consumption of such products and with consumption of such products in excess of labeled serving sizes.

III. Current Provisions of the Ephedrine Alkaloids Proposal

Despite this action to withdraw the proposed dietary ingredient level and duration of use limit, and related provisions of the ephedrine alkaloids proposal, there remain provisions that the agency is not withdrawing in this notice. These provisions concern FDA's proposed prohibition on the use of ingredients with stimulant effects with dietary supplements containing ephedrine alkaloids (§ 111.100(d)) and the proposed warning statement (§ 111.100(g)).

FDA proposed in § 111.100(d) to require that no ingredient, or ingredient that contains a substance, that has a known stimulant effect (e.g, sources of caffeine, yohimbine) may be included in a dietary supplement that contains ephedrine alkaloids. FDA proposed this provision in response to the many adverse events that had been reported to the agency. These adverse events involved the use of dietary supplements that contain ephedrine alkaloids in combination with other ingredients, some with known physiological or pharmacological effects, including kola nut, yohimbe, willow bark, senna, and Uva ursi (see Ref. 164 of the proposed rule (Docket No. 95N–0304)). These adverse events suggested that the other ingredients may act in combination with the ephedrine alkaloids to produce more frequent, more severe, or potentially different patterns of adverse effects than those noted with the use of ephedrine alkaloids alone.

In the ephedrine alkaloids proposal, FDA also tentatively concluded that a warning statement on the labels of dietary supplements containing ephedrine alkaloids is necessary, in conjunction with dietary ingredient limitations and other requirements proposed in that document, to protect the public health. The warning statements proposed in § 111.100(g) contained several elements, including cautions that consumers not use the product if they have certain diseases or health conditions or are using certain drugs, and to stop the use of the product if they develop certain signs or symptoms. As noted in the preamble to the ephedrine alkaloids proposal, persons having certain diseases or taking specific medications known to interact with ephedrine alkaloids are at risk of suffering adverse events with the use of dietary supplements containing ephedrine alkaloids. Generally, use of ephedrine alkaloids at any intake level by these persons is contraindicated. For these persons a warning label statement can be a useful means of alerting them to potential consequences that can result from the use of the product. In addition, many consumers who are unaware that they are sensitive to the effect of ephedrine alkaloids may not recognize the significance of early warning signs and symptoms as potential indicators of more serious side effects (e.g., dizziness or severe headache may be early symptoms of hypertension or stroke). Under these circumstances, a warning statement could provide information on what actions the consumer should take if certain symptoms occur (62 FR 30678 at 30700).

The agency has not at this time concluded that it will finalize the provisions in § 111.100(d) and (g). Rather, the agency intends to consider whether to finalize these provisions, or take additional or alternative regulatory action, after it receives public input on the significance of new information collected by the agency about the safety of dietary supplements containing ephedrine alkaloids.

IV. Continued Monitoring and Followup

Although FDA is withdrawing certain provisions of the ephedrine alkaloids proposal, FDA continues to have a public health concern with respect to the use of dietary supplements containing ephedrine alkaloids. The agency will continue to monitor and provide appropriate followup on adverse events associated with the use of these products. In a notice of availability published elsewhere in this issue of the **Federal Register**, FDA is seeking public input about the significance of new information collected by the agency about the safety of dietary supplements containing ephedrine alkaloids. The agency is also requesting the submission of any other information that the submitters believe is relevant to such a safety assessment. Should additional information suggest that additional action is necessary, FDA will consider what action is appropriate, and take appropriate steps to protect consumers and the public health.

V. Enforcement

Withdrawal of certain provisions of the ephedrine alkaloids proposal does not limit the agency's discretion to initiate enforcement actions with respect to ephedrine alkaloids containing dietary supplements. For example, circumstances may warrant enforcement action against a dietary supplement containing ephedrine alkaloids if an evaluation of the relevant facts show a health hazard or that the product is otherwise adulterated or misbranded.

FDA maintains its street drug alternative policy, as articulated in the preamble to the ephedrine alkaloids proposal, which states that because alternatives to illicit street drugs are not intended to supplement the diet, products that purport to be or that are represented, either expressly or implicitly, for use as alternatives to street drugs are not dietary supplements within the meaning of section 201(ff) of

the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(ff)). (See 62 FR 30678 at 30699 and 30700). FDA is publishing elsewhere in this issue of the **Federal Register** a notice announcing the availability of a guidance entitled ''Street Drug Alternatives.'' The guidance is intended to inform industry and the public that FDA considers any product that is promoted as a street drug alternative to be an unapproved new drug and a misbranded drug in violation of the act. To date, the agency has taken action against several products marketed as alternatives to illicit street drugs, and it may do so in the future, as well.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the proposed rule published on June 4, 1997 (62 FR 30678), is withdrawn in part for § 111.100(a), (b), (c), (e), and (f).

Dated: March 28, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–8109 Filed 3–31–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 275

[Notice No. 894]

RIN 1512–AB71

Implementation of Public Law 105–33, Section 9302, Requiring the Qualification of Tobacco Products Importers.

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Notice of proposed rulemaking; reopening of comment period.

SUMMARY: This document reopens the comment period for Notice No. 888, a notice of proposed rulemaking cross-referenced to temporary regulations, published in the **Federal Register** on December 22, 1999. ATF has received a request to extend the comment period in order to provide sufficient time for all interested parties to respond to the issues raised in the notice.

DATES: Written comments must be received on or before May 3, 2000.

ADDRESSES: Send written comments to: Chief, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 50221, Washington, DC 20091–0221, Attention: Notice Number 888.

FOR FURTHER INFORMATION CONTACT: Clifford A. Mullen by writing to Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW, Washington, DC 20226, by phone at 202–927–8210, or by e-mail at *alcohol/tobacco@atfhq.atf.treas.gov.*

SUPPLEMENTARY INFORMATION:

Background

On December 22, 1999, ATF published a notice of proposed rulemaking (NPRM) cross-referenced to temporary regulations in the **Federal Register** soliciting comments from the public and industry on proposed regulations implementing the provisions of the Balanced Budget Act of 1997, Public Law 105–33. These provisions amended the Internal Revenue Code of 1986 to require that, beginning January 1, 2000, importers of tobacco products qualify for a permit to conduct that activity (Notice No. 888; 64 FR 71955).

The comment period for Notice No. 888 was scheduled to close on February 22, 2000. Prior to the close of the comment period, ATF received a request from a manufacturer of tobacco products, RJ Reynolds Tobacco Company to extend the comment period. RJ Reynolds stated that it needed additional time to coordinate the comments of several departments within the company which have an interest in the importation of tobacco products.

In consideration of the above, ATF finds that a reopening of the comment period is warranted. Thus, the comment period is being reopened for an additional 30 days until May 3, 2000. The Bureau believes that a comment period totaling 90 days is a sufficient amount of time for all interested parties to respond.

Disclosure

Copies of this notice, Notice No. 888, and the written comments will be available for public inspection during normal business hours at: ATF Public Reading Room, Room 6480, 650 Massachussetts Avenue, NW, Washington DC.

Drafting Information. The author of this document is Clifford A. Mullen, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 275

Administrative practices and procedures, Authority delegations, Cigarette papers and tubes, Cigars and cigarettes, Claims, Customs duties and inspections, Electronic funds transfers, Excise taxes, Imports, Labeling, Packaging and containers, Penalties, Reporting and record keeping requirements, Seizures and forfeitures, Surety bonds, U.S. Possessions, Warehouses.

Authority and Issuance

This notice is issued under the authority in 26 U.S.C. 7805.

Signed: March 22, 2000.

Bradley A. Buckles,

Director.

[FR Doc. 00–8113 Filed 3–31–00; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900–AJ23

Information Collection Needed in VA's Flight-Training Programs

AGENCIES: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: We propose to amend our educational assistance and educational benefit regulations concerning flight-training courses for which the Department of Veterans Affairs (VA) pays for eligible students. In this regard, we propose to require that flight schools offering such flight-training courses maintain records regarding students to whom VA makes payments. The proposed rule is intended to provide information to VA for determining compliance with requirements for VA payments to students for pursuing flight-training courses. Also, when VA, rather than a separate State entity, is the approving agency, the proposed rule is intended to provide information to VA for determining whether to approve a flight-training course.

DATES: Comments must be received on or before June 2, 2000.

ADDRESSES: Mail or hand-deliver written comments to: Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Ave., NW, Room 1154, Washington, DC 20420; or fax comments to (202) 273–9289; or e-mail comments to ''OGCRegulations@mail.va.gov''. Comments should indicate that they are submitted in response to ''RIN 2900–AJ23.'' All comments received will be available for public inspection in the Office of Regulations Management, Room 1158, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: William G. Susling, Jr., Education