

delivered for introduction into interstate commerce on or after July 1, 1983, shall comply with the regulations.

The agency has determined pursuant to 21 CFR 25.24(d)(13) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In accordance with the Regulatory Flexibility Act (Pub. L. 96-354 (5 U.S.C. 601)), FDA has considered the effect this regulation would have on small businesses. The petitioner in this action is the owner of a small business hampered in the sale of its products by a standard of identity that prevents its product from being marketed under a commonly recognized name. This proposed action provides the petitioner, as well as an unknown number of similar businesses, options in the manufacture and marketing of their products. These options are expected to produce economic benefits of an undetermined magnitude. The agency concludes that the proposed action is not restrictive, because the effect of this regulation is to permit additional flexibility in manufacturing to both large and small businesses. The agency certifies that the publication of this proposal will not have a significant economic impact on a substantial number of small entities.

PART 135—FROZEN DESSERTS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), it is proposed that Part 135 be amended as follows:

1. By adding new § 135.115, to read as follows:

§ 135.115 Goat's milk ice cream.

(a) *Description.* Goat's milk ice cream is the food prepared in the same manner prescribed in § 135.110 for ice cream, and complies with all the provisions of § 135.110, except that the only optional dairy ingredients that may be used are those in paragraph (b) of this section; caseinates may not be used; and paragraphs (e)(1) and (f) of § 135.110 shall not apply.

(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are liquid, concentrated, or dry goat's skim milk; goat's milk; and goat's cream.

(c) *Nomenclature.* The name of the food is "goat's milk ice cream" or, alternatively, "ice cream made with goat's milk", except that when the egg yolk solids content of the food is in excess of that specified for ice cream in paragraph (a) of § 135.110, the name of the food is "goat's milk frozen custard" or, alternatively, "frozen custard made with goat's milk", or "goat's milk french ice cream", or, alternatively, "french ice cream made with goat's milk", or "goat's milk french custard ice cream", or, alternatively, "french custard ice cream made with goat's milk".

(d) *Label declaration.* Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

2. By adding new § 135.125, to read as follows:

§ 135.125 Goat's milk ice milk.

(a) *Description.* Goat's milk ice milk is the food prepared in the same manner prescribed in § 135.115 for goat's milk ice cream, except that paragraph (c) shall not apply, and which complies with all the requirements of § 135.120(a) (1), (2), (4), (5), (6), and (7) for ice milk.

(b) *Nomenclature.* The name of the food is "goat's milk ice milk" or, alternatively, "ice milk made with goat's milk".

Interested persons may, on or before February 5, 1982, submit to the Dockets Management Branch (HFA-305) (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.

Dated: November 27, 1981.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Withdrawal of Proposal To Place Tiletamine and Zolazepam Into Schedule I

AGENCY: Drug Enforcement
Administration, Justice.

ACTION: Withdrawal of proposed rule.

SUMMARY: This notice withdraws the proposal to control the substances tiletamine and zolazepam under Schedule I of the Controlled Substances Act and reaffirms the proposal to control, under Schedule III, preparations containing equal amounts of those substances.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION: On July 9, 1981, the Administrator of the Drug Enforcement Administration published a Notice of Proposed Rulemaking in which he proposed to control tiletamine and zolazepam under Schedule I of the Controlled Substances Act (21 U.S.C. 801, *et seq.*) and further proposed to control preparations containing equal amounts of the base equivalents of those substances under Schedule III of the Act. The notice was published at 46 FR 35529. The proposed actions were to be finalized if and when the Food and Drug Administration approved the New Animal Drug Application (NADA) for Telazol, a preparation containing equal amounts of the base equivalents of tiletamine HC1 and zolazepam HC1. Interested parties were given until September 9, 1981 to submit written comments or objections with regard to these proposals.

Comments concerning the proposed actions were received from the American Association of Zoo Veterinarians and from counsel for the Warner-Lambert Company, the manufacturer of Telazol. The American Association of Zoo Veterinarians did not object to the placement of the combination drug product in Schedule III, but did object to the placement of the individual components into Schedule I. The Association felt that the Schedule I treatment of the individual ingredients would discourage or prevent the manufacture of the combination product. Warner-Lambert, the holder of the NADA for Telazol, also objected to the placement of tiletamine and zolazepam into Schedule I. The manufacturer asserted that neither of the substances met the criteria for Schedule I and further argued that the two ingredients were immediate precursors of Telazol which, as such, could not be placed into a schedule higher than that in which Telazol was placed. Warner-Lambert indicated that the placement of tiletamine and zolazepam into Schedule I would place such undue hardship upon the company as to render the

manufacture of Telazol uneconomical. Finally, the manufacturer argued that Telazol should be controlled under Schedule IV rather than Schedule III. Warner-Lambert has requested a hearing with respect to these issues.

The Acting Administrator has considered this matter at some length. The placement of preparations containing equal amounts of tiletamine and zolazepam into Schedule III is consistent with the scientific and medical evaluation of the Acting Assistant Secretary for Health and with the independent evaluation of the Acting Administrator in accordance with the provisions of 21 U.S.C. 811 (b) and (c). The regulatory requirements for the manufacture, distribution, dispensing and administration of Schedule III and IV substances are, for all intents and purposes, identical. The regulatory burden associated with the manufacture of Schedule III substances is no greater than that for substances in Schedule IV. Furthermore, no data has been presented to cast doubt upon the original determination that Telazol best fits in Schedule III. Accordingly, the Acting Administrator reaffirms the proposed placement of preparations containing equal amounts of the base equivalents of tiletamine and zolazepam into Schedule III. This control action will be finalized when the FDA approves the NADA for the marketing of Telazol.

The Acting Administrator believes that the issues raised with respect to the proposed Schedule I treatment of the ingredients, tiletamine and zolazepam, merit further consideration. However, deliberation over these issues should not impede the marketing of a substance for which there appears to be a need in veterinary medicine. Accordingly, the Acting Administrator withdraws the proposal to place tiletamine and zolazepam into Schedule I.

In the opinion of the Acting Administrator, the request for a hearing in this matter was directed at the proposed scheduling of the substances, tiletamine and zolazepam, into Schedule I and not at the proposed placement of the combination product into Schedule III. Any necessity for a hearing should be obviated by the withdrawal of the proposal to control tiletamine and zolazepam in Schedule I. Accordingly, the request for a hearing is denied at this time. In the event that the manufacturer still desires a hearing with respect to the control of Telazol, the Acting Administrator will consider a written request made on or before January 7, 1982.

Dated: December 1, 1981.

Francis M. Mullen, Jr.,
Acting Administrator, Drug Enforcement
Administration.

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INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency For International Development
22 CFR Part 203

Registration of Agencies for Voluntary
Foreign Aid

AGENCY: Agency for International
Development, IDCA.

ACTION: Proposed rule.

SUMMARY: The Agency for International Development is amending this regulation to clarify the purpose of registration and emphasize that applicants must be private and voluntary in character.

DATE: Comments must be submitted on or before January 7, 1982.

ADDRESS: Comments should be submitted to: Robert S. McClusky, Agency for International Development, FVA/PVC/PLD, Room 227, SA-8, Washington, D.C. 20523.

FOR FURTHER INFORMATION CONTACT: Robert S. McClusky, (703) 235-1844.

SUPPLEMENTARY INFORMATION:

1. Section 203.1 Purpose.

This restatement of the purposes of registration establishes that registration provides a mechanism for identifying which organizations are eligible for A.I.D. resources intended for private and voluntary organizations (PVOs), e.g., matching, institutional/development support or operational program grants, or the subventions of Pub. L. 99 commodities, excess property or ocean freight reimbursement. This section recognizes that A.I.D. always has had, and continues to have, authority to make grants to other nonprofit, nongovernment organizations without their being registered.

This section also takes note that "it is not the purpose of registration to make or enable to be made any representation to the public concerning the meaning of being registered." This addition emphasizes that registration serves A.I.D. purposes and is not a consumer protection process designed to respond to the need for information on the part of the contributing public.

2. Section 203.2 Conditions of registration and documentation

requirements for U.S. private and voluntary organizations.

One overall change in format has been made which effects this entire section. The registration documentation requirements have been combined with the conditions of registration, i.e., documentation requirements now immediately follow each condition. The previous format separated the conditions from the related documentation requirements.

In the following discussion, each condition will be discussed separately with the exception of condition 3 in which there was no substantive change.

Condition No. 1. This condition has been modified to include information previously contained elsewhere in the regulation as to the types of organizations not eligible to apply for registration. Additionally, the categories of organizations ineligible to apply have been expanded to include churches or organizations whose primary purpose is to engage in religious activities. This addition resolves a confusion flowing from the phrase "other than religious," used elsewhere in the text. This phrase has been open to the interpretation that a church could register provided it conducted other than religious activities.

Condition 2 has been expanded from the previous requirements that the applicant simply be "nongovernmental," to require that an applicant be a "private, nongovernmental organization which receives funds from private, U.S. sources * * *" with the stipulation that " * * * at least 20% of the funding (excluding in-kind contributions) for its overseas program costs (excluding in-kind contributions) in the last audit year are from private U.S. sources."

"Funds from private, U.S. sources" is defined as " * * * cash received from private, nongovernmental, U.S.C sources, e.g., support and revenue from private individuals, groups, foundations and/or corporations. In-kind contributions are not included. Funds received directly or indirectly from the U.S. Government (or state or local governments), the United Nations or any other public international organization, or foreign governments or institutions are not included."

This addition recognizes A.I.D.'s decision that, in practical terms, "private" refers mainly to the balance between private and public financial resources, and that a tightening up in the application of the test of privateness is desirable to reemphasize our interest in mobilizing private sector resources, and protecting the independence of PVOs.

"Overseas program costs" are defined as the " * * * costs of all voluntary