

**DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE**

Food and Drug Administration

[21 CFR Part 155]

[Docket No. 75P-0322]

CANNED VEGETABLES

**Canned Peas; Standards of Identity,
Quality, and Fill of Containers**

Correction

In FR Doc. 77-15769 appearing at page 29014, in the issue for Tuesday, June 7, 1977, make the following changes:

1. In the table labeled "3. Food Additives" on page 29015, in the column of numbers to the left side of the table, the 5th number in the list should be "3.3.2" instead of "3.2.2." Under the column labeled "Maximum level of use," opposite the figure "3.4.3," "50 mg/kg total Ca in the final product," should read "350 mg/kg total Ca in the final product."

2. In the 4th line from the top of the second column on page 29017, the number "1," should be "1.0."

3. On page 29018, in the second column under the paragraph labeled "4. Tenderness," in the third line, "much," should be "such."

Note.—This correction is republished without change from the issue of Thursday, June 23, 1977.

[21 CFR Part 820]

[Docket No. 75N-0140]

MEDICAL DEVICES

**Public Hearing on Proposed Good
Manufacturing Practice Regulations**

AGENCY: Food and Drug Administration.

ACTION: Notice of hearing.

SUMMARY: This is an announcement that a public hearing before the Commissioner of Food and Drugs will be held on August 5, 1977, to receive comments and views from interested persons on the proposed regulations for Good Manufacturing Practice (GMP) for Medical Devices. The Commissioner will consider the administrative record of the hearing, along with other received information, in preparing a final regulation.

DATES: Notices of appearance by July 28, 1977; the hearing will be held on August 5, 1977.

ADDRESS: Written notices of appearance to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Leonard J. Stauffer, Bureau of Medical Devices (HFK-123), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910, (301-427-7194).

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 (Pub. L. 94-295), amending the Federal Food, Drug, and Cosmetic Act (hereinafter referred to as "the act"), became law on May 28, 1976. Section 520(f) of the amended act (21 U.S.C. 360j(f)) provides the agency with the authority to prescribe regulations requiring that the methods used in, and facilities and controls used for, the manufacture, packing, storage, and installation of devices, conform to current GMP requirements.

A proposed GMP regulation for medical devices was published in the FEDERAL REGISTER of March 1, 1977 (42 FR 11998). Interested persons are advised that a hearing will be held on the proposal in accordance with regulations relating to public hearings before the Commissioner (21 CFR Part 15) and that persons who wish to present comments and views at the hearing must file a written notice of appearance. This notice also sets forth specific issues on which the Commissioner seeks comments and views.

The hearing announced in this notice will provide an open forum for the presentation of comments and views on the proposed GMP regulations. Although views may be presented on any subject of the proposed action, several specific areas of consideration on which the Commissioner seeks well-documented comments are:

(1) Definitions of: "Critical device." "Critical component." "Critical operation."

(2) The extent to which the proposal would have an impact on the economy under the criteria established by Executive Order No. 11821 as amended, OMB Circular A-107 and agency guidelines.

The hearing will begin at 9 a.m. on August 5, 1977 at the Departmental Auditorium, HEW North Building, 330 Independence Ave. SW., Washington, D.C. The presiding officer will be David M. Link, Director, Bureau of Medical Devices, and members of the Device Good Manufacturing Practice Advisory Committee will attend the hearing. This committee has been established under section 520(f) of the act to advise and make recommendations to the Commissioner in regard to device GMP regulations promulgated under the act.

Although the regular comment period for the proposal will end June 29, 1977, the record of the hearing will remain open for 15 days subsequent to the date of the hearing, August 5, 1977, to permit submission of additional written comments and views limited to matters discussed at the hearing.

In preparing a final regulation, the Commissioner will consider the administrative record of this hearing along with all other written comments received during the comment period specified in the proposal, as well as the recommendations of the advisory committee.

Persons wishing to comment or present views at this hearing must file by July 28, 1977 a written notice of appearance under 21 CFR 15.21 with the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers

Lane, Rockville, Md. 20857. The notice of appearance shall contain the Hearing Clerk Docket No. [75N-0140]; the name, address and telephone number of the person desiring to make a statement; business affiliation, if any; a summary of the presentation; and the approximate amount of time being requested for the presentation. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations. The Commissioner may require joint presentations by persons with common interests. He will allocate the time available for the hearing among the persons who properly file a notice of appearance and will make a schedule of the hearing available to such persons. Persons may use their allotted time on any aspect of the proposed action, consistent with the conduct of a reasonable and orderly hearing. Formal written statements on the issues may be presented to the presiding officer on the day of the hearing for inclusion in the record.

The hearing will be open to the public. At the discretion of the presiding officer, and as time permits, any interested person in attendance may be heard with respect to matters relevant to the proposed GMP regulations.

Dated: June 22, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 77-18392 Filed 6-23-77; 10:22 am]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Part 1308]

**SCHEDULES OF CONTROLLED
SUBSTANCES**

Placement of Lorazepam in Schedule IV

AGENCY: Drug Enforcement Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: This is a proposed rule to place the drug lorazepam into schedule IV of the Controlled Substances Act. This proposal is being initiated in response to a letter from the Acting Assistant Secretary for Health, Department of HEW, which requested that lorazepam be placed into schedule IV. This proposal would require that the manufacture, distribution, dispensing, importation, and exportation of lorazepam be subject to controls for schedule IV controlled substances.

DATES: Comment deadline: All comments, objections, and requests for a hearing must be received on or before July 28, 1977.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, United States Department of Justice, 1405 I Street NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative.

FOR FURTHER INFORMATION CONTACT:

Howard McClain (202-382-5676).

SUPPLEMENTARY INFORMATION:

On February 9, 1977, the Acting Assistant Secretary for Health, on behalf of the Secretary of Health, Education and Welfare sent a letter to the Administrator of the Drug Enforcement Administration which recommended that the drug lorazepam be placed into schedule IV of the Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801-966)).

Enclosed with the letter from the Acting Assistant Secretary was a document which listed factors which the Act requires the Secretary to consider and the summarized considerations of the Secretary in recommending control for lorazepam.

The factors considered by the Secretary for lorazepam were:

1. Its actual or relative potential for abuse.
2. Scientific evidence of its pharmacologic effect, if known.
3. The state of current scientific knowledge regarding the drug or other substance.
4. Its history and current pattern of abuse.
5. The scope, duration, and significance of abuse.
6. What, if any, risk there is to the public health.
7. Its psychic or physiological dependence liability.
8. Whether the substance is an immediate precursor of a substance already controlled under the Controlled Substances Act.

Also enclosed with the Acting Assistant Secretary's letter was a document which Wyeth Laboratories, Inc. had submitted to the FDA, containing pertinent information concerning the abuse potential and dependence liability of its product lorazepam.

The Drug Enforcement Administration has conducted a review of lorazepam, which has included the following:

1. Published scientific and medical literature from the United States and other nations regarding this drug;
2. Material submitted to the Drug Enforcement Administration by the Department of Health, Education, and Welfare in support of the Acting Assistant Secretary's February 9, 1977, letter requesting control for lorazepam;
3. Materials on file with the Food and Drug Administration, and the Drug Enforcement Administration; and
4. The legislative history of the Controlled Substances Act.

Based upon the investigations and review of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), the Administrator of the Drug Enforcement Administration finds that:

1. Based on information now available, lorazepam has a low potential for abuse relative to the drugs or other substances currently listed in schedule III.

2. Lorazepam will, upon the issuance of New Drug Application by the Food and Drug Administration, have a currently accepted medical use in treatment in the United States.

3. Abuse of lorazepam may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

Therefore, under the authority vested in him by the Act and by regulations of the Department of Justice, the Administrator of the Drug Enforcement Administration hereby proposes that § 1308.14 (b) of Title 21 of the Code of Federal Regulations (CFR) be amended to read as follows:

§ 1308.14 Schedule IV.

(b) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(11) Lorazepam	2885
(12) Mebutamate	2800
(13) Meprobamate	2820
(14) Methohexital	2264
(15) Methyphenobarbital (mephobarbital)	2250
(16) Oxazepam	2835
(17) Paraldehyde	2585
(18) Petrichoral	2591
(19) Phenobarbital	2285
(20) Prazepam	2764

All interested persons are invited to submit their comments or objections in writing regarding this proposal. These comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, United States Department of Justice, 1405 I Street NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative. All such submissions must be received on or before July 28, 1977.

In the event that an interested party submits objections to these proposals which present reasonable grounds for these rules not to be finalized and requests a hearing in accordance with 21 CFR 1308.45, the party will be notified by registered mail of the time and place that the hearing will be held. If any objections which are submitted do not present reasonable grounds, the party will be so advised by registered mail.

If no objections presenting grounds for a hearing on these proposals are re-

ceived within the time limitations, or all interested parties waive or are deemed to waive their opportunity for a hearing or to participate in a hearing, the Administrator, after giving consideration to written comments and objections, will issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Dated: June 21, 1977.

PETER B. BENSINGER,
Administrator, Drug
Enforcement Administration.

[FR Doc. 77-18408 Filed 6-27-77; 8:46 am]

DEPARTMENT OF STATE

[22 CFR Part 123]

[Docket No. SD-133]

INTERNATIONAL TRAFFIC IN ARMS

Licenses for Export of Firearms

AGENCY: Department of State.

ACTION: Proposed rule.

SUMMARY: This proposal would revoke a rule under the International Traffic in Arms regulations which allows persons leaving the U.S. to export three or fewer firearms and accompanying ammunition for their personal use without an export license. The proposal is intended to prevent the possible circumvention of the policies and purposes of the regulations.

DATES: Comments must be received by July 20, 1977.

ADDRESS: Send comments to William B. Robinson, Office of Munitions Control, Department of State, 2201 C Street NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:

Clyde Bryant, 703-235-9758.

SUPPLEMENTARY INFORMATION: Section 123.31 of 22 CFR was originally adopted to allow U.S. citizens to export firearms for their personal use without an export license. A recent study by the Office of Munitions Control, however, reveals that the exemption is rarely used by U.S. citizens. On the contrary, it is used repeatedly by non-U.S. citizens some of whom enter and leave the United States several times in one year. By permitting them to carry with them firearms and cartridges without a license, the exemption creates undesirable risks that weapons may be disposed of abroad in circumvention of the policies and purposes of the International Traffic in Arms regulations. The destination of these unlicensed firearms could include countries to which the U.S. Government would not license the export of firearms.

In consideration of the foregoing, the Department of State proposes the following change in 22 CFR 123.31:¹

¹ For a document suspending § 123.31 until the completion of this rulemaking proceeding, see FR Doc. 77-18581, appearing under 22 CFR in the Rules and Regulations section of this issue of the FEDERAL REGISTER.