Internet through FERC's Homepage (http://www.ferc.fed.us) using the CIPS Link or the Energy Information Online icon. The full text of this document will be available on CIPS in ASCII and WordPerfect 6.1 format. CIPS is also available through the Commission's electronic bulletin board service at no charge to the user and may be accessed using a personal computer with a modem by dialing 202–208–1397, if dialing locally, or 1–800–856–3920, if dialing long distance. To access CIPS, set your communications software to 19200, 14400, 12000, 9600, 7200, 4800, 2400, or 1200 bps, full duplex, no parity, 8 data bits and 1 stop bit. User assistance is available at 202–208–2474 or by E-mail to CipsMaster@FERC.fed.us.

This document is also available through the Commission's Records and Information Management System (RIMS), an electronic storage and retrieval system of documents submitted to and issued by the Commission after November 16, 1981. Documents from November 1995 to the present can be viewed and printed. RIMS is available in the Public Reference Room or remotely via Internet through FERC's Homepage using the RIMS link or the Energy Information Online icon. User assistance is available at 202–208–2222, or by E-mail to RimsMaster@FERC.fed.us.

Finally, the complete text on diskette in WordPerfect format may be purchased from the Commission's copy contractor, RVJ International, Inc. RVJ International, Inc., is located in the Public Reference Room at 888 First Street, N.E., Washington, D.C. 20426.

The Federal Energy Regulatory Commission (Commission) is proposing to expand its procedural regulations governing the authorization of natural gas facilities and services, and is considering revising its procedural regulations governing applications for licenses for hydroelectric projects.[1] The proposed regulations are intended to offer prospective applicants seeking to construct, operate or abandon natural gas facilities or services the option, in appropriate circumstances and prior to filing an application, of using a collaborative process to resolve significant issues. In addition, a significant portion of the environmental review process could be completed as part of the pre-filing collaborative process. This pre-filing collaborative process is comparable to the process the Commission recently adopted with respect to applications for hydroelectric licenses, amendments and exemptions and, like those regulations, is optional and is designed to be adaptable to the facts and circumstances of the particular case. The proposed regulations would not delete or replace any existing regulations. Finally, the Commission is considering whether the existing collaborative process for hydroelectric license and exemption applications, as well as the proposed collaborative process for natural gas facilities and services, should be made mandatory.

Staff technical conferences will be held to provide an overview of the proposed pre-filing collaborative process and to respond to questions. Conferences will be held at 9:00 a.m. on November 10, 1998, at the Houston Airport Marriott, 18700 Kennedy Boulevard, Houston, Texas, and on November 18, 1998, at the Chicago Marriott Downtown, 540 North Michigan Avenue, Chicago, Illinois. These conferences are designed as workshops in which Commission staff will present information and respond to questions concerning the proposed collaborative process as an aid to assist participants in developing comments in response to and as requested in the September 30, 1998 Notice of Proposed Rulemaking. Accordingly, there will be no transcript and statements made in the context of the workshops will not become part of the record in this proceeding. All parties—particularly those with experience with collaborative processes, whether at this agency or in another context—are invited to attend.

David P. Boergers,

Secretary.

[FR Doc. 98–29590 Filed 11–5–98; 8:45 am]

BILLING CODE 6717–01–M

[1] *See* 84 FERC ¶ 61,346 (September 30, 1998).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 98N–0786]

General Hospital and Personal Use Devices: Proposed Classification of Liquid Chemical Sterilants and General Purpose Disinfectants

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify both liquid chemical sterilants intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use, and general purpose disinfectants intended to process noncritical medical devices and equipment surfaces. Under the proposal, liquid chemical sterilants would be classified into class II (special controls) and general purpose disinfectants would be classified into class I (general controls). FDA also proposes to exempt general purpose disinfectants from the premarket notification requirements. The agency is publishing in this document the recommendations of the General Hospital and Personal Use Devices Panel (the Panel) regarding the classification of these devices. After considering public comments on the proposed classification, FDA will publish a final regulation classifying these devices. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices.

DATES: Written comments by February 4, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Devices Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA) (Pub. L. 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1)

Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(I) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval. Consistent with the act and the regulations, FDA consulted the Panel, regarding the classification of the device.

The FDAMA added a new section 510(l) to the act (21 U.S.C. 360(l)). New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. Hereafter, these are referred to as ''reserved criteria.'' FDA has considered the general purpose disinfectants in accordance with the reserved criteria and determine that the devices do not require premarket notification. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA.

In 1980, when other general hospital and personal use devices were classified (45 FR 69678 to 69737, October 21, 1980), FDA inadvertently omitted liquid chemical germicides, such as liquid chemical sterilants and general purpose disinfectants from the classification process. In subsequent years, FDA actively regulated only liquid chemical germicides that were used as accessories to specific class II devices, such as hemodialyzers. FDA began actively regulating all liquid chemical germicides in the early 1990's following efficacy testing by FDA for the Environmental Protection Agency (EPA) and publication of the 1993 General Accounting Office (GAO) report on Hospital Sterilants (Ref. 1). Liquid chemical germicides were regulated as accessories to other devices with the level of regulation applicable coinciding with the classification of the other devices. FDA also determined that two categories of liquid chemical germicides existed, liquid chemical sterilants and general purpose disinfectants.

The first category consists of liquid chemical sterilants which are intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use. Semicritical medical devices contact mucous membranes or nonintact skin during use, while critical devices contact normally sterile tissue or body spaces.

The second category of liquid chemical germicides consists of general purpose disinfectants which are intended to process noncritical medical devices and medical equipment surfaces, and can be used to preclean or decontaminate critical or semicritical medical devices prior to terminal sterilization or high level disinfection. Noncritical medical devices only make topical contact with intact skin of the body.

In addition to being regulated by FDA, certain liquid chemical germicides are regulated by EPA as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). On June 4, 1993, a memorandum of understanding (MOU) was signed between FDA and EPA (Refs. 3 and 4). The purpose of the MOU was to resolve the confusion and burden of dual regulation and, at the same time, ensure that the safety and efficacy requirements of both statutes are met.

In 1996, liquid chemical sterilants used for processing critical and semicritical medical devices were exempted from the definition of a pesticide under FIFRA with passage of the Food Quality Protection Act of 1996 (FQPA) and are no longer regulated by EPA. FDA now has sole regulatory jurisdiction over liquid chemical sterilants and high level disinfectants used to process reusable critical and semicritical medical devices. Regulatory authority over general purpose disinfectants was not affected by FQPA. Therefore, the MOU remains in effect for general purpose disinfectants, and the dual regulatory requirements for these germicides continue until the rulemaking process for classification of the germicides is completed.

II. Recommendations of the Panel

During a public meeting which was held on July 18, 1995, the Panel made the following recommendations regarding the classification of liquid chemical sterilants and general purpose disinfectants.

A. Identification

The Panel recommended that the devices be identified as follows:

A liquid chemical sterilant is a germicide intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use. Semicritical devices make contact with mucous membranes or nonintact skin during use. Critical devices contact normally sterile tissue or body spaces during use (Refs. 5 and 6).

A general purpose disinfectant is a germicide intended to process noncritical medical devices and medical equipment surfaces. A general purpose disinfectant can be used to preclean or decontaminate critical or semicritical medical devices prior to terminal sterilization or high level disinfection. Noncritical medical devices only make topical contact with intact skin of the body (Refs. 5 and 6).

B. Recommended Classification of the Panel

The Panel unanimously recommended that liquid chemical sterilants be classified into class II. The Panel believed that class II with the special controls (the 510(k) guidance document (Ref. 2), voluntary standards, and user information and training) would provide reasonable assurance of the safety and effectiveness of the devices.

The Panel recommended that general purpose disinfectants be classified into class I and that the devices should be exempt from the premarket notification procedures.

C. Summary of Reasons for Recommendation

After reviewing the information provided by FDA, and after

consideration of the open discussions during the Panel meeting and the Panel members' personal knowledge of and clinical experience with the device systems, the Panel gave the following reasons in support of its recommendations to classify the generic type of liquid chemical sterilants for use as the terminal step in processing critical and semicritical medical devices prior to patient use into class II, and general purpose disinfectants for use in processing noncritical medical devices and medical equipment surfaces into class I:

1. The Panel believes that liquid chemical sterilants should be classified into class II because special controls, in addition to general controls, would be necessary to provide reasonable assurance of the safety and effectiveness of the devices, and there is sufficient information to establish special controls to provide such assurance.

2. The Panel believes that general purpose disinfectants should be classified into class I because general controls would provide reasonable assurance of the safety and effectiveness of the devices. In addition to the Panel's recommendation, FDA has considered general purpose disinfectants in accordance with the reserved criteria of new section 510(l) of the act and determined that the general purpose disinfectants do not require premarket notification.

D. Summary of Data Upon Which the Recommendation is Based

The Panel noted that liquid chemical sterilants include peracetic acid, hydrogen peroxide, chlorine dioxide, and glutaraldehyde. These substances are used to sterilize or high level disinfect heat sensitive medical devices such as flexible endoscopes. Toxicity studies have shown hydrogen peroxide and peracetic acid to be nontoxic, nonsensitizing and, at most, minimally irritating. In addition, these chemicals, as well as chlorine dioxide, are used at low concentrations and readily degrade to nontoxic compounds, such as water and molecular oxygen (Refs. 7, 8, and 9).

Toxicity studies have shown glutaraldehyde to be a skin, eye, and respiratory system irritant and a skin sensitizer. Since glutaraldehyde does not readily degrade, long-term effects of its residue as a skin or eye irritant are of concern (Refs. 10 and 11). Although some injuries and deaths have been reported following the use of these chemicals as sterilants and disinfectants, they have been primarily associated with failure of the user to follow the manufacturer's directions for use (Ref. 12).

The Panel noted that general purpose disinfectants include alcohols, chlorines, iodophors, phenolics, and quaternary ammonium compounds. The hazards and adverse effects of these substances are well known (Ref. 8). Toxicity is minimal because these substances are used at low concentrations on equipment surfaces and noncritical devices that only contact intact skin during use.

The use of liquid chemical sterilants and general purpose disinfectants on medical devices is based on the infection control classification system devised by E. H. Spaulding (Refs. 13 and 14), and adopted by infection control practitioners, FDA, and the Centers for Disease Control and Prevention. Spaulding's system is predicated on the relative risks associated with the use of medical devices. According to Spaulding's system, devices that contact normally sterile tissues or body spaces during use are termed critical devices. Critical devices should be sterilized prior to use.

Devices that contact mucous membranes, which can provide a barrier to many, but not all microorganisms, are termed semicritical devices. Semicritical devices should be sterilized prior to use when practical, or should undergo high level disinfection (a high level disinfectant is a sterilant used for a shorter contact time and that kills all microbial pathogens except large numbers of bacterial endospores). General purpose disinfectants can be used to clean or decontaminate critical and semicritical devices prior to a terminal sterilization or high level disinfection process.

E. Risks to Health

The following three risks are associated with the use of germicides such as liquid chemical sterilants and general purpose disinfectants: (1) Nosocomial infection, (2) toxicity associated with chemical exposure, and (3) damage to medical devices.

The formulation of a germicide plays an important role in the effectiveness of the germicide on the device. If the formulation is inadequate for its intended use or if the germicide is improperly used, the sterilization or disinfection process will be ineffective. As a result, the processed device may serve as a potential vector for the transmission of infectious microorganisms to the next patient.

In the **Federal Register** of December 6, 1996 (61 FR 64755), FDA announced the availability of a draft guidance document entitled ''Draft Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Germicides'' (Ref. 2). In the **Federal Register** of May 22, 1997 (62 FR 28055), FDA extended the period to comment on the draft guidance until August 20, 1997.

The guidance document suggests that manufacturers of these devices are to submit, for review and evaluation, microbiological studies supporting all germicidal claims, and adequate instructions for use. EPA registration for general purpose disinfectants requires similar information.

With regard to chemical exposure, health-care workers who process medical devices with either liquid chemical sterilants or general purpose disinfectants are potentially exposed to toxic substances during use of the germicides. In addition, the patient may be exposed to germicide residues if the device is inadequately rinsed.

Labeling recommendations in the guidance document include warnings and precautions regarding the proper use and handling of liquid chemical sterilants and other toxic substances. Additionally, the guidance document recommends a toxicological assessment of germicide residues remaining following rinsing. EPA registration of general purpose disinfectants requires similar information.

Lastly, both liquid chemical sterilants and general purpose disinfectants may damage medical devices causing them to function improperly or create areas that cannot be effectively cleaned, disinfected or sterilized. The guidance document recommends that data demonstrating device materials compatibility with the liquid chemical germicides be included in the 510(k).

F. Special Controls

Based on the available information, FDA believes that, in addition to general controls, the special controls discussed as follows are adequate to address the risks to health which were identified previously.

1. The 510(k) guidance document;
2. Voluntary standards; and
3. User information and training.

The guidance document provides 510(k) applicants with specific directions regarding data and information that should be submitted to FDA in a 510(k) submission for liquid chemical germicides. The document incorporates voluntary standards and guidelines from professional organizations as part of its recommendation for performance testing. Compliance with the recommendations made in the document for liquid chemical sterilants is important in preventing nosocomial infections.

Voluntary standards provide assurance of consistency and uniformity in germicide effectiveness.

User information and training programs are critical to ensure that users have full knowledge and assume responsibility for the safe and effective use of the liquid chemical sterilants.

Adherence to these special controls can provide the user community a greater assurance of effectiveness and appropriate use in order to minimize nosocomial infection through improperly sterilized or disinfected reusable medical devices.

III. Proposed Classification

FDA believes that liquid chemical sterilants should be classified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the devices, and there is sufficient information to establish special controls to provide such assurance.

FDA believes that general purpose disinfectants should be classified into class I because general controls under the act and the EPA registration requirements would provide reasonable assurance of safety and effectiveness of these products. FDA also believes that these devices do not meet the reserved criteria of new section 510(l) of the act and should be exempt from premarket notification requirements.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. General Accounting Office, Report to the Ranking Minority Member Committee on Government Operations, House of Representatives, Hospital Sterilants: Insufficient FDA Regulation May Pose a Public Health Risk, GAO/HRD–93–79, June 1993.

2. FDA, Center for Devices and Radiological Health, Office of Device Evaluation, ''Draft Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Germicides,'' January 1992; revised April 26, 1995.

3. Memorandum of Understanding Between the Food and Drug Administration, Public Health Service, Department of Health and Human Services and the Environmental Protection Agency, Notice Regarding Matters of Mutual Responsibility—Regulation of Liquid Chemical Germicides Intended for Use on Medical Devices, June 4, 1993.

4. Amendment to the June 4, 1993, Memorandum of Understanding Between the Food and Drug Administration, Public Health Service, Department of Health and Human Services and the Environmental Protection Agency, June 30, 1994.

5. General Hospital and Personal Use Devices Panel, Thirtieth Meeting, Transcript, July 18, 1995.

6. General Hospital and Personal Use Devices Panel, Thirtieth Meeting, Summary of Minutes, July 18, 1995.

7. Malchesky, P. S., ''Peracetic Acid and Its Application to Medical Instrument Sterilization,'' *Artificial Organs*, vol. 17, no. 3, pp. 147–152, 1993.

8. Block, S. S., ''Peroxygen Compounds,'' *Disinfection, Sterilization, and Preservation*, pp. 167–181, Philadelphia, 1991.

9. Dychdala, G. R., ''Chlorine and Chlorine Compounds,'' *Disinfection, Sterilization, and Preservation*, pp. 131–151, Philadelphia, 1991.

10. Scott, E. M., and S. P. Gorman, ''Glutaraldehyde,'' in *Disinfection, Sterilization, and Preservation*, pp. 596–614, Philadelphia, 1991.

11. Australian Government Publishing Service, ''Priority Existing Chemical No.3, Glutaraldehyde,'' pp. 53–62, Canberra, July 1994.

12. Spach, D. H., F. E. Silverstein, and W. E. Stamm, ''Transmission of Infection by Gastrointestinal Endoscopy and Bronchoscopy,'' *Annals of Internal Medicine*, vol. 118, no. 2, pp. 117–128, 1993.

13. Spaulding, E. H., ''Role of Chemical Disinfection in the Prevention of Nosocomial Infections,'' Proceedings of International Conference on Nosocomial Infections, pp. 247–254, Chicago, 1970.

14. Spaulding, E. H., ''Chemical Disinfection and Antisepsis in the Hospital,'' *Journal of Hospital Research*, vol. 9, pp. 5–31, 1972.

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule classifying these devices eliminates duplicative registration, and may enable additional small competitors to enter the marketplace by eliminating the cost of complying with two sets of requirements, it will impose no significant economic impact on any small entities. The agency therefore certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Submission of Comments and Proposed Dates

Interested persons may, on or before February 4, 1999, submit to the Dockets Management Branch (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.

FDA proposes that any final regulation that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 880 be amended to read as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Sections 880.6885 and 880.6890 are added to subpart G to read as follows:

§ 880.6885 Liquid chemical sterilants.

(a) *Identification*. A liquid chemical sterilant is a germicide that is intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use. Critical devices make contact with normally sterile tissue or body spaces during use. Semicritical devices make contact with mucous membranes or nonintact skin during use.

(b) *Classification*. Class II (special controls). (Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Germicides, voluntary standards, and user information and training.)

§ 880.6890 General purpose disinfectants.

(a) *Identification*. A general purpose disinfectant is a germicide intended to process noncritical medical devices and equipment surfaces. A general purpose disinfectant can be used to preclean or decontaminate critical or semicritical medical devices prior to terminal sterilization or high level disinfection. Noncritical medical devices make only topical contact with intact skin of the body.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

Dated: October 2, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–29566 Filed 11–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 4, 19, 24, 194, 250 and 251

[Notice No. 869; Ref: Notice No. 859]

RIN 1512–AB71

Implementation of Public Law 105–34, Sections 908, 910 and 1415, Related to Hard Cider, Semi-generic Wine Designations, and Wholesale Liquor Dealers' Signs (97–2523)

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

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

SUMMARY: This notice reopens the comment period for Notice No. 859, a notice of proposed rulemaking, published in the **Federal Register** on August 21, 1998. ATF has received requests 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 December 7, 1998.

ADDRESSES: Send written comments to: Chief, Regulations Division; Bureau of Alcohol, Tobacco and Firearms; P.O. Box 50221; Washington, DC 20091–0221; *ATTN: Notice No. 859.* See the Public Participation section of this notice for alternative means of commenting.

FOR FURTHER INFORMATION CONTACT: Marjorie D. Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (202–927–8230), mdruhf@atfhq.atf.treas.gov.

SUPPLEMENTARY INFORMATION:

Background

On August 21, 1998, ATF published a temporary rule and an associated notice of proposed rulemaking in the **Federal Register** soliciting comments from the public and industry on three sections of the Taxpayer Relief Act of 1997, (Treasury Decision ATF–398, 63 FR 44779, and Notice No. 859, 63 FR 44819).

The comment period for Notice No. 859 closed on October 20, 1998. Prior to the close of the comment period ATF received requests from Ms. Cheryl A. Lau, a cider industry representative, Mr. Kirk Seggie, Winery Manager of Andrés Wines (B.C.) Ltd., Mr. Kenton E. Kidd, of the California Apple Commission, and Mr. Thomas E. Dalldorf, Sr., Publisher of *Celebrator Beer News*, to extend the comment period for a short time. All these writers stated that potential commenters in the apple industry were in the middle of the apple harvest and would not be able to take time to provide the sort of historical and technical information requested in the notice. They suggested an extension until late November to afford these interested persons an opportunity to comment. In consideration of the above, ATF finds that a reopening of the comment period is warranted.

Public Participation

ATF requests comments on the temporary regulations published in Treasury decision ATF–398 (63 FR 44779) from all interested persons. Comments received on or before the closing date will be carefully considered. Comments received after that date will be given the same consideration if it is practicable to do so, but assurance of consideration cannot be given except as to comments received on or before the closing date.

Comments may be submitted by facsimile transmission (FAX) to (202) 927–8602, provided the comments: (1) Are legible, (2) are 8½″×11″ in size, (3) contain a written signature, and (4) are three pages or less in length. This limitation is necessary to assure reasonable access to the equipment. Comments sent by FAX in excess of three pages will not be accepted. Facsimile transmitted comments will be treated as originals.

Comments may also be sent by electronic mail (e-mail) to nprm@atfhq.atf.treas.gov, provided (1) the message is entitled ''Comment on Notice No. 859; (2) the name and company affiliation, if any, of the commenter is contained in the body of the message; and (3) the message contains no attachments, special characters or encryption. E-mail comments will be printed and filed with comments submitted on paper and by facsimile transmission.

Receipt of comments will not be acknowledged. ATF will not recognize any material in comments as confidential. Comments may be disclosed to the public. Any material which the commenter considers to be confidential or inappropriate for disclosure to the public should not be included in the comment. The name of the person submitting the comment is not exempt from disclosure. During the comment period, any person may request an opportunity to present oral testimony at a public hearing. However, the Director reserves the right, in light