

lots, batches, or other units of a medical device, if the Center Director determines that compliance with such labeling requirement could adversely affect the safety, effectiveness, or availability of such devices that are or will be included in the Strategic National Stockpile.

(b)(1)(i) A Strategic National Stockpile official or any entity that manufactures (including labeling, packing, relabeling, or repackaging), distributes, or stores devices that are or will be included in the Strategic National Stockpile may submit, with written concurrence from a Strategic National Stockpile official, a written request for an exception or alternative described in paragraph (a) of this section to the Center Director.

(ii) The Center Director may grant an exception or alternative described in paragraph (a) of this section on his or her own initiative.

(2) A written request for an exception or alternative described in paragraph (a) of this section must:

(i) Identify the specified lots, batches, or other units of the medical device that would be subject to the exception or alternative;

(ii) Identify the labeling provision(s) listed in paragraph (f) of this section that are the subject of the exception or alternative request;

(iii) Explain why compliance with the labeling provision(s) could adversely affect the safety, effectiveness, or availability of the specified lots, batches, or other units of a medical device that are or will be held in the Strategic National Stockpile;

(iv) Describe any proposed safeguards or conditions that will be implemented so that the labeling of the device includes appropriate information necessary for the safe and effective use of the device, given the anticipated circumstances of use of the device;

(v) Provide a draft of the proposed labeling of the specified lots, batches, or other units of the medical device subject to the exception or alternative; and

(vi) Provide any other information requested by the Center Director in support of the request.

(c) The Center Director must respond in writing to all requests under this

section. The Center Director may impose appropriate conditions when granting such an exception or alternative under this section.

(d) A grant of an exception or alternative under this section will include any safeguards or conditions deemed appropriate by the Center Director so that the labeling of devices subject to the exception or alternative includes the information necessary for the safe and effective use of the device, given the anticipated circumstances of use.

(e) If the Center Director grants a request for an exception or alternative to the labeling requirements under this section:

(1) The Center Director may determine that the submission and grant of a written request under this section satisfies the provisions relating to premarket notification submissions under §807.81(a)(3) of this chapter.

(2)(i) For a Premarket Approval Application (PMA)-approved device, the submission and grant of a written request under this section satisfies the provisions relating to submission of PMA supplements under §814.39 of this chapter; however,

(ii) The grant of the request must be identified in a periodic report under §814.84 of this chapter.

(f) The Center Director may grant an exception or alternative under this section to the following provisions of this chapter, to the extent that the requirements in these provisions are not explicitly required by statute:

- (1) § 801.1(d);
- (2) § 801.60;
- (3) § 801.61;
- (4) § 801.62;
- (5) § 801.63;
- (6) § 801.109; and
- (7) Part 801, subpart H.

[72 FR 73601, Dec. 28, 2007]

### Subpart E—Other Exemptions

#### § 801.150 Medical devices; processing, labeling, or repackaging.

(a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked, in substantial quantity at an establishment other than that where

originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of section 502(b) and (f) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such device is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such device in such establishment as will insure, if such specifications are followed, that such device will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such device from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(b) An exemption of a shipment or other delivery of a device under paragraph (a)(1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(c) An exemption of a shipment or other delivery of a device under paragraph (a)(2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such paragraph (a)(2).

(d) An exemption of a shipment or other delivery of a device under paragraph (a)(2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(2) Upon refusal by the operator of the establishment where such device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

(e) As it is a common industry practice to manufacture and/or assemble, package, and fully label a device as sterile at one establishment and then ship such device in interstate commerce to another establishment or to a contract sterilizer for sterilization, the Food and Drug Administration will initiate no regulatory action against the device as misbranded or adulterated when the nonsterile device is labeled sterile, provided all the following conditions are met:

(1) There is in effect a written agreement which:

(i) Contains the names and post office addresses of the firms involved and is signed by the person authorizing such shipment and the operator or person in charge of the establishment receiving the devices for sterilization.

(ii) Provides instructions for maintaining proper records or otherwise accounting for the number of units in each shipment to insure that the number of units shipped is the same as the number received and sterilized.

(iii) Acknowledges that the device is nonsterile and is being shipped for further processing, and

(iv) States in detail the sterilization process, the gaseous mixture or other media, the equipment, and the testing method or quality controls to be used by the contract sterilizer to assure that the device will be brought into full compliance with the Federal Food, Drug, and Cosmetic Act.

(2) Each pallet, carton, or other designated unit is conspicuously marked to show its nonsterile nature when it is introduced into and is moving in interstate commerce, and while it is being

held prior to sterilization. Following sterilization, and until such time as it is established that the device is sterile and can be released from quarantine, each pallet, carton, or other designated unit is conspicuously marked to show that it has not been released from quarantine, e.g., “sterilized—awaiting test results” or an equivalent designation.

### Subparts F–G [Reserved]

### Subpart H—Special Requirements for Specific Devices

#### § 801.405 Labeling of articles intended for lay use in the repairing and/or refitting of dentures.

(a) The American Dental Association and leading dental authorities have advised the Food and Drug Administration of their concern regarding the safety of denture reliners, repair kits, pads, cushions, and other articles marketed and labeled for lay use in the repairing, refitting, or cushioning of ill-fitting, broken, or irritating dentures. It is the opinion of dental authorities and the Food and Drug Administration that to properly repair and properly refit dentures a person must have professional knowledge and specialized technical skill. Laymen cannot be expected to maintain the original vertical dimension of occlusion and the centric relation essential in the proper repairing or refitting of dentures. The continued wearing of improperly repaired or refitted dentures may cause acceleration of bone resorption, soft tissue hyperplasia, and other irreparable damage to the oral cavity. Such articles designed for lay use should be limited to emergency or temporary situations pending the services of a licensed dentist.

(b) The Food and Drug Administration therefore regards such articles as unsafe and misbranded under the Federal Food, Drug, and Cosmetic Act, unless the labeling:

(1)(i) Limits directions for use for denture repair kits to emergency repairing pending unavoidable delay in obtaining professional reconstruction of the denture;

(ii) Limits directions for use for denture reliners, pads, and cushions to

temporary refitting pending unavoidable delay in obtaining professional reconstruction of the denture;

(2) Contains in a conspicuous manner the word “emergency” preceding and modifying each indication-for-use statement for denture repair kits and the word “temporary” preceding and modifying each indication-for-use statement for reliners, pads, and cushions; and

(3) Includes a conspicuous warning statement to the effect:

(i) For denture repair kits: “*Warning—For emergency repairs only.* Long term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. This kit for emergency use only. See Dentist Without Delay.”

(ii) For denture reliners, pads, and cushions: “*Warning—For temporary use only.* Longterm use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until a Dentist Can Be Seen.”

(c) Adequate directions for use require full information of the temporary and emergency use recommended in order for the layman to understand the limitations of usefulness, the reasons therefor, and the importance of adhering to the warnings. Accordingly, the labeling should contain substantially the following information:

(1) For denture repair kits: Special training and tools are needed to repair dentures to fit properly. Home-repaired dentures may cause irritation to the gums and discomfort and tiredness while eating. Long term use may lead to more troubles, even permanent changes in bones, teeth, and gums, which may make it impossible to wear dentures in the future. For these reasons, dentures repaired with this kit should be used only in an emergency until a dentist can be seen. Dentures that don’t fit properly cause irritation and injury to the gums and faster bone loss, which is permanent. Dentures that don’t fit properly cause gum changes that may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible.

(2) For denture reliners, pads, and cushions: Use of these preparations or