

§ 201.161

21 CFR Ch. I (4–1–03 Edition)

(c) An exemption of a shipment or other delivery of a drug 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) of this section.

(d) An exemption of a shipment or other delivery of a drug 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 drug 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 drug is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

[41 FR 6911, Feb. 13, 1976, as amended at 64 FR 400, Jan. 5, 1999]

§ 201.161 Carbon dioxide and certain other gases.

(a) Carbon dioxide, cyclopropane, ethylene, helium, and nitrous oxide gases intended for drug use are exempted from the requirements of § 201.100(b) (2), (3), and (c)(1) provided the labeling bears, in addition to any other information required by the Federal Food, Drug, and Cosmetic Act, the following:

(1) The warning statement “Warning—Administration of (name of gas) may be hazardous or contraindicated. For use only by or under the supervision of a licensed practitioner who is experienced in the use and administration of (name of gas) and is familiar with the indications, effects, dosages, methods, and frequency and duration of administration, and with the hazards, contraindications, and side effects and the precautions to be taken”; and

(2) Any needed directions concerning the conditions for storage and warnings against the inherent dangers in the handling of the specific compressed gas.

(b) This labeling exemption does not apply to mixtures of any one or more

of these gases with oxygen or with each other.

(c) Regulatory action may be initiated with respect to any article shipped within the jurisdiction of the Act contrary to the provisions of this section after 60 days following publication of this section in the FEDERAL REGISTER.

Subpart F—Labeling Claims for Drugs in Drug Efficacy Study

§ 201.200 Disclosure of drug efficacy study evaluations in labeling and advertising.

(a)(1) The National Academy of Sciences—National Research Council, Drug Efficacy Study Group, has completed an exhaustive review of labeling claims made for drugs marketed under new-drug and antibiotic drug procedures between 1938 and 1962. The results are compiled in “Drug Efficacy Study, A Report to the Commissioner of Food and Drugs from the National Academy of Sciences (1969).” As the report notes, this review has made “an audit of the state of the art of drug usage that has been uniquely extensive in scope and uniquely intensive in time” and is applicable to more than 80 percent of the currently marketed drugs. The report further notes that the quality of the evidence of efficacy, as well as the quality of the labeling claims, is poor. Labeling and other promotional claims have been evaluated as “effective,” “probably effective,” “possibly effective,” “ineffective,” “ineffective as a fixed combination,” and “effective but,” and a report for each drug in the study has been submitted to the Commissioner.

(2) The Food and Drug Administration is processing the reports, seeking voluntary action on the part of the drug manufacturers and distributors in the elimination or modification of unsupported promotional claims, and initiating administrative actions as necessary to require product and labeling changes.

(3) Delays have been encountered in bringing to the attention of the prescribers of prescription items the conclusions of the expert panels that reviewed the promotional claims.