

§ 310.4 Biologics; products subject to license control.

(a) Except for radioactive biological products intended for human use, a new drug shall not be deemed to be subject to section 505 of the act if it is a drug licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended (42 U.S.C. 201 *et seq.*)) or under the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832 (21 U.S.C. 151 *et seq.*)).

(b) A radioactive biological product (as defined in § 600.3(ee) of this chapter) intended for human use is subject to section 505 of the act. Any license for such a radioactive biological product which is issued under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended (42 U.S.C. 201 *et seq.*)) and which has not been revoked or suspended as of August 25, 1975 shall constitute an approved new drug application in effect under the same terms and conditions as set forth in such license and such portions of the establishment license relating to such product, which include data and information required under part 314 of this chapter for a new drug application. Any such radioactive biological product for which licensure under the Public Health Service Act is pending on August 25, 1975 shall, upon determination that it is acceptable for licensure, be approved as a new drug application in lieu of issuance of a biological product license.

[40 FR 31312, July 25, 1975]

§ 310.6 Applicability of “new drug” or safety or effectiveness findings in drug efficacy study implementation notices and notices of opportunity for hearing to identical, related, and similar drug products.

(a) The Food and Drug Administration's conclusions on the effectiveness of drugs are currently being published in the FEDERAL REGISTER as Drug Efficacy Study Implementation (DESI) Notices and as Notices of Opportunity for Hearing. The specific products listed in these notices include only those that were introduced into the market through the new drug procedures from 1938–62 and were submitted for review by the National Academy of Sciences-National Research Council (NAS-NRC), Drug Efficacy Study Group. Many

products which are identical to, related to, or similar to the products listed in these notices have been marketed under different names or by different firms during this same period or since 1962 without going through the new drug procedures or the Academy review. Even though these products are not listed in the notices, they are covered by the new drug applications reviewed and thus are subject to these notices. All persons with an interest in a product that is identical, related, or similar to a drug listed in a drug efficacy notice or a notice of opportunity for a hearing will be given the same opportunity as the applicant to submit data and information, to request a hearing, and to participate in any hearing. It is not feasible for the Food and Drug Administration to list all products which are covered by an NDA and thus subject to each notice. However, it is essential that the findings and conclusions that a drug product is a “new drug” or that there is a lack of evidence to show that a drug product is safe or effective be applied to all identical, related, and similar drug products to which they are reasonably applicable. Any product not in compliance with an applicable drug efficacy notice is in violation of section 505 (new drugs) and/or section 502 (misbranding) of the act.

(b)(1) An identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as of any drug moiety related in chemical structure or known pharmacological properties.

(2) Where experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs would conclude that the findings and conclusions, stated in a drug efficacy notice or notice of opportunity for hearing, that a drug product is a “new drug” or that there is a lack of evidence to show that a drug product is safe or effective are applicable to an identical, related, or similar drug product, such product is affected by the notice. A combination drug product containing a drug that is identical, related, or similar to a drug named in a notice may also be subject to the findings and conclusions in a notice that a drug

product is a “new drug” or that there is a lack of evidence to show that a drug product is safe or effective.

(3) Any person may request an opinion on the applicability of such a notice to a specific product by writing to the Food and Drug Administration at the address shown in paragraph (e) of this section.

(c) Manufacturers and distributors of drugs should review their products as drug efficacy notices are published and assure that identical, related, or similar products comply with all applicable provisions of the notices.

(d) The published notices and summary lists of the conclusions are of particular interest to drug purchasing agents. These agents should take particular care to assure that the same purchasing policy applies to drug products that are identical, related, or similar to those named in the drug efficacy notices. The Food and Drug Administration applies the same regulatory policy to all such products. In many instances a determination can readily be made as to the applicability of a drug efficacy notice by an individual who is knowledgeable about drugs and their indications for use. Where the relationships are more subtle and not readily recognized, the purchasing agent may request an opinion by writing to the Food and Drug Administration at the address shown in paragraph (e) of this section.

(e) Interested parties may submit to the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, HFD-300, 5600 Fishers Lane, Rockville, MD 20857, the names of drug products, and of their manufacturers or distributors, that should be the subject of the same purchasing and regulatory policies as those reviewed by the Drug Efficacy Study Group. Appropriate action, including referral to purchasing officials of various government agencies, will be taken.

(f) This regulation does not apply to OTC drugs identical, similar, or related to a drug in the Drug Efficacy Study unless there has been or is notification in the FEDERAL REGISTER that a drug will not be subject to an OTC panel re-

view pursuant to §§ 330.10, 330.11, and 330.5 of this chapter.

[39 FR 11680, Mar. 29, 1974, as amended at 48 FR 2755, Jan. 21, 1983; 50 FR 8996, Mar. 6, 1985; 55 FR 11578, Mar. 29, 1990]

Subpart B—Specific Administrative Rulings and Decisions

§ 310.100 New drug status opinions; statement of policy.

(a) Over the years since 1938 the Food and Drug Administration has given informal advice to inquirers as to the new drug status of preparations. These drugs have sometimes been identified only by general statements of composition. Generally, such informal opinions were incorporated in letters that did not explicitly relate all of the necessary conditions and qualifications such as the quantitative formula for the drug and the conditions under which it was prescribed, recommended, or suggested. This has contributed to misunderstanding and misinterpretation of such opinions.

(b) These informal opinions that an article is “not a new drug” or “no longer a new drug” require reexamination under the Kefauver-Harris Act (Public Law 87-781; 76 Stat. 788-89). In particular, when approval of a new drug application is withdrawn under provisions of section 505(e) of the Federal Food, Drug, and Cosmetic Act, a drug generally recognized as safe may become a “new drug” within the meaning of section 201(p) of said act as amended by the Kefauver-Harris Act on October 10, 1962. This is of special importance by reason of proposed actions to withdraw approval of new drug applications for lack of substantial evidence of effectiveness as a result of reports of the National Academy of Sciences—National Research Council on its review of drug effectiveness; for example, see the notice published in the FEDERAL REGISTER of January 23, 1968 (33 FR 818), regarding rutin, quercetin, et al.

(c) Any marketed drug is a “new drug” if any labeling change made after October 9, 1962, recommends or suggests new conditions of use under which the drug is not generally recognized as safe and effective by qualified experts. Undisclosed or unreported side