§ 330.11 NDA deviations from applicable monograph.

A new drug application requesting approval of an OTC drug deviating in any respect from a monograph that has become final shall be in the form required by §314.50 of this chapter, but shall include a statement that the product meets all conditions of the applicable monograph except for the deviation for which approval is requested and may omit all information except that pertinent to the deviation.

[39 FR 11741, Mar. 29, 1974, as amended at 55 FR 11581, Mar. 29, 1990]

§ 330.12 Status of over-the-counter (OTC) drugs previously reviewed under the Drug Efficacy Study (DESI).

(a) There were 420 OTC drugs reviewed in the Drug Efficacy Study (a review of drugs introduced to the market through new drug procedures between 1938 and 1962). A careful review has been made of the reports on these drugs to determine those drugs for which implementation may be deferred without significant risk to the public health, pending review by appropriate OTC drug advisory review panels and promulgation of a monograph.

(b) On and after April 20, 1972, a number of notices were published in the Federal Register concerning previously unpublished OTC drugs reviewed by the National Academy of Sciences-National Research Council Drug Efficacy Study Group. Only the evaluations and comments of the panels were published, with no conclusions of the Commissioner of Food and Drugs. Those publications were for the purpose of giving interested persons the benefit of the Academy’s opinions. For those products, and also for OTC drug products previously published with the Commissioner’s conclusions (except for the products listed in paragraphs (b) (1) and (2) of this section, all requests for data, revised labeling, requests for new drug applications, abbreviated new drug applications, updating supplements, data to support less than effective claims, if any, etc., are deferred, and such OTC drug products are instead subject to the OTC drug review in their appropriate classes pursuant to the procedures established in this subpart.

(1) The requirements of the following DESI announcements are not deferred (the reference document may also pertain to prescription drugs):


(iii) Certain Insulin Preparations (DESI 4236), published in the Federal Register of April 9, 1971 (36 FR 6842).


(v) Antiperspirants and Deodorants Containing Neomycin Sulfate (DESI 11048) for which an order revoking provisions for certification or release was published in the Federal Register of December 5, 1972 (37 FR 23820) and has been stayed by the filing of objections.

(vi) Thorexin Cough Medicine (DESI 11160) for which a notice of opportunity for hearing was published in the Federal Register of February 2, 1973 (38 FR 3210).

(vii) Antibiotic susceptibility discs (DESI 90235) for which an order providing for certain discs to be certified and removing provisions for certification of other discs was published in the Federal Register of September 30, 1972 (37 FR 20525) and has been stayed by the filing of objections notice of which was published in the Federal Register of March 15, 1973 (38 FR 7007).

(2) Deferral of requirements is not appropriate when an announcement has been published and has been followed by a final order classifying a drug either as lacking substantial evidence of effectiveness or as not shown to be safe. These products will be removed from the market, if they have not already been removed. Regulatory action will also be undertaken against identical, similar and related products (21 CFR 310.6). Deferral of requirements is not appropriate for the following (the referenced document may also pertain to prescription drugs):

(i) Certain Sulfonamide-Decongestant Nasal Preparation (DESI 4850), for
which notice of withdrawal of approval of new drug applications was published in the Federal Register of October 24, 1970 (35 FR 16605, 16606).

(ii) Eskay’s Theranates, containing strychnine, sodium, and calcium glycerophosphates, thiamine hydrochloride, alcohol, and phosphoric acid (DESI 2220), for which notice of withdrawal of approval of the new drug application was published in the Federal Register of February 18, 1971 (36 FR 3152).

(iii) The following topical drugs (DESI 1726), for which notice of withdrawal of new drug applications was published in the Federal Register of August 28, 1971 (36 FR 17368):

(a) Rhulitol Solution, containing tannic acid, chlorobutanol, phenol, camphor, alum, and isopropyl alcohol.

(b) Zirnox Topical Lotion, containing phenytoloxamine citrate and zirconium oxide.

(iv) Menacyl Tablets, containing aspirin, menadione, and ascorbic acid (DESI 6383), for which notice of withdrawal of approval of the new drug application was published in the Federal Register of July 23, 1970 (35 FR 11827).

(v) Curad Medicated Adhesive Bandage containing sulfathiazole (DESI 4964), for which notice of withdrawal of approval of the new drug application was published in the Federal Register of December 31, 1969 (34 FR 20441).

(vi) Drugs Containing Rutin, Quercetin, Hesperidin, or any Bioflavonoids (DESI 5960), for which notice of withdrawal of approval of new drug applications was published in the Federal Register of July 3, 1970 (35 FR 10872, 10873) and October 17, 1970 (35 FR 16332).

A further notice of opportunity for hearing with respect to the drugs covered by the October 17, 1970 Federal Register notice will be published at a later date.

(vii) Antibiotics in Combination with Other Drugs for Nasal Use (DESI 7561), for which an order revoking provision for certification was published in the Federal Register of August 6, 1971 (36 FR 14469) and confirmed in the Federal Register of October 28, 1971 (36 FR 20686).

(viii) Antibiotic Troches (DESI 8328), for which an order revoking provision for certification was published in the Federal Register of July 14, 1971 (36 FR 13088) and confirmed in the Federal Register of October 9, 1971 (36 FR 19695).

(ix) Certain Drugs Containing Oxyphenisatin or Oxyphenisatin Acetate (DESI 10732), for which notices of withdrawal of approval of new drug applications were published in the Federal Register of February 1, 1972 (37 FR 2460), and March 9, 1973 (38 FR 6419).

(x) Curad Medicated Adhesive Bandage containing tyrothricin-nitrofurazone (DESI 6896), for which an order revoking provision for certification was published March 14, 1972 (37 FR 5294), and confirmed in the Federal Register of July 6, 1972 (37 FR 13254).

(xi) Candette Cough Gel (DESI 11562), for which notice of withdrawal of approval of the new drug application was published in the Federal Register of November 19, 1972 (37 FR 25249).

(xii) Certain OTC Multiple-Vitamin Preparations for Oral Use containing excessive amounts of vitamin D and/or vitamin A (DESI 97), for which notice of withdrawal of approval of the new drug applications was published in the Federal Register of November 29, 1972 (37 FR 25249).

(xiii) Certain Sulfonamide-Containing Preparations for Topical Ophthalmic or Otic Use (DESI 368, for which a notice of withdrawal of approval was published in the Federal Register of February 2, 1973 (38 FR 3208).

(xiv) Those parts of the publication entitled “Certain Mouthwash and Garlic Preparations” (DESI 2855) pertaining to Tyrolaris Mouthwash, containing tyrothricin, panthenol, and alcohol, for which an order revoking provision for certification was published in the Federal Register of February 2, 1967 (32 FR 1172) prior to the drug efficacy study implementation.

(c) Manufacturers and distributors should take notice that the information on OTC drugs provided by the Drug Efficacy Study review is valuable information as to the deficiencies in the data available to support indications for use. They are encouraged to perform studies to obtain adequate evidence of effectiveness for the review of OTC drugs which is already in progress.
§ 330.13 Conditions for marketing ingredients recommended for over-the-counter (OTC) use under the OTC drug review.

(a) Before the publication in the Federal Register of an applicable proposed monograph, an OTC drug product that contains: (1) An active ingredient limited, on or after May 11, 1972, to prescription use for the indication and route of administration under consideration by an OTC advisory review panel, and not thereafter exempted from such limitation pursuant to § 310.200 of this chapter, or

(2) An active ingredient at a dosage level higher than that available in an OTC drug product on December 4, 1975, shall be regarded as a new drug within the meaning of section 201(p) of the act for which an approved new drug application is required.

(b)(1) An OTC drug product that contains: (i) An active ingredient limited, on or after May 11, 1972, to prescription use for the indication and route of administration under consideration by an OTC advisory review panel, and not thereafter exempted from such limitation pursuant to § 310.200 of this chapter, or

(ii) An active ingredient at a dosage level higher than that available in an OTC drug product on December 4, 1975, which ingredient and/or dosage level is classified by the panel in category I (conditions subject to § 330.10(a)(6)(i)) shall be regarded as a new drug within the meaning of section 201(p) of the act for which an approved new drug application is required if marketed for OTC use prior to the date of publication in the Federal Register of a proposed monograph.

(2) An OTC drug product covered by paragraph (b)(1) of this section which is marketed after the date of publication in the Federal Register of a proposed monograph but prior to the effective date of a final monograph shall be subject to the risk that the Commissioner may not accept the panel’s recommendation and may instead adopt a different position that may require repackaging, recall, or other regulatory action. The Commissioner may state such position at any time by notice in the Federal Register, either separately or as part of another document;