

**§ 416.969a Exertional and nonexertional limitations.**

(a) *General.* \* \* \* When we decide whether you can do your past relevant work (see §§ 416.920(f) and 416.994(b)(5)(vi)), we will compare our assessment of your residual functional capacity with the demands of your past relevant work. If you cannot do your past relevant work, we will use the same residual functional capacity assessment along with your age, education, and work experience to decide if you can adjust to any other work which exists in the national economy. (See §§ 416.920(g) and 416.994(b)(5)(vii).)

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■ 27. Amend § 416.994 by revising the first sentence of paragraph (b)(5)(vi) to read as follows:

**§ 416.994 How we will determine whether your disability continues or ends, disabled adults.**

\* \* \* \* \*

(b) \* \* \*  
(5) \* \* \*

(vi) *Step 6.* your impairment(s) is severe, we will assess your current ability to do substantial gainful activity in accordance with § 416.960. \* \* \*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 310**

[Docket No. 1980N-0050]

RIN 0910-AA01

**Anorectal Drug Products for Over-the-Counter Human Use**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule establishing that any over-the-counter (OTC) drug product containing a combination of hydrocortisone and pramoxine hydrochloride (HCl) for anorectal use is not generally recognized as safe and effective and is misbranded. This combination product is not currently marketed OTC. This final rule discusses data on the combination of hydrocortisone and pramoxine HCl that were still under review when an earlier final rule on OTC anorectal drug products was issued. This rule is part of

FDA's ongoing review of OTC drug products.

**DATES:** This rule is effective September 25, 2003.

**FOR FURTHER INFORMATION CONTACT:** Michael T. Benson, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

**SUPPLEMENTARY INFORMATION:****I. Background**

In the *Federal Register* of May 27, 1980 (45 FR 35576), FDA published an advance notice of proposed rulemaking to establish a monograph for OTC anorectal drug products together with the recommendations of the Advisory Review Panel on OTC Hemorrhoidal Drug Products (the Hemorrhoidal Panel), which was the advisory review panel responsible for evaluating the data on the active ingredients in this class of drugs. The agency's tentative final monograph (TFM) on OTC anorectal drug products was published in the *Federal Register* of August 15, 1988 (53 FR 30756). Hydrocortisone as a single ingredient or in combination with pramoxine HCl was not discussed in the TFM. In response to the TFM, the agency received a submission, containing data, information, analyses, views, legal arguments, and a hearing request, to support monograph status for a combination OTC drug product containing hydrocortisone and pramoxine HCl for use as an anti-inflammatory, antipruritic, anesthetic agent (Ref. 1). The requester asked that: (1) The definition section of the proposed anorectal monograph (§ 346.3 (21 CFR 346.3)) be amended to provide for a drug that has anti-inflammatory properties, such as hydrocortisone, (2) hydrocortisone be allowed to be combined with other appropriate ingredients at OTC strengths, including a topical anesthetic such as pramoxine HCl and, (3) a combination of hydrocortisone 0.5 percent and 1 percent pramoxine HCl be generally recognized as safe and effective.

When the OTC anorectal drug products final monograph was published on August 3, 1990 (55 FR 31776 at 31779), the hearing request relating to hydrocortisone individually and in combination had not been evaluated and, therefore, was not addressed in that document. After publication of the final rule, the agency responded to the submission (Ref. 1) and stated that: (1) It does not provide sufficient evidence to demonstrate that each of the active ingredients in the combination product contributes to the

claimed effects and (2) it has not been shown that the combination is generally recognized as safe and effective, whether under the TFM for OTC external analgesic drug products (48 FR 5852, February 8, 1983), the TFM or FM for OTC anorectal drug products, current regulations, or the agency's OTC combination drug product guidelines. The agency's detailed comments are on file in the Division of Dockets Management (Ref. 2).

Subsequently, the requester submitted additional information (Ref. 3). In this final rule, the agency responds to the additional information and includes the combination of hydrocortisone with pramoxine HCl as a nonmonograph (not generally recognized as safe and effective) anorectal drug product in new § 310.545(a)(26)(xi) (21 CFR 310.545(a)(26)(xi)). Any such product marketed OTC would be subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the effective date of this final rule.

**II. The Agency's Final Conclusions on Hydrocortisone Individually and in Combination With Pramoxine HCl for Anorectal Use**

The requester contended (Ref. 3) that the proposed combination meets, both from a scientific and legal perspective, the agency's OTC combination drug product policy in that a combination of hydrocortisone (0.25 to 1 percent) and pramoxine HCl 1 percent, is generally recognized as safe and effective for use in OTC drug products to relieve symptoms associated with idiopathic pruritus ani, such as anorectal swelling, pain, itching, and burning. The requester asked the agency to amend the OTC external analgesic drug products TFM and the anorectal drug products FM to include an external analgesic-anorectal OTC drug product containing the active ingredients hydrocortisone and pramoxine HCl. In the alternative, the requester asked for an oral hearing.

The requester's arguments and the agency's responses follow:

(Comment 1) Hydrocortisone is a proposed Category I ingredient and; therefore, FDA considers it safe and effective for OTC use. The ingredient is included in the OTC external analgesic drug products TFM (55 FR 6932 at 6951, February 27, 1990). FDA considers hydrocortisone safe and effective to relieve swelling and itching associated with various skin conditions, including anal itching (55 FR 6932 at 6933).

(Agency response) The agency agrees that hydrocortisone as a single ingredient is safe and effective for OTC use for the claims proposed in