

**HAND-DELIVERED****Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751****WARNING LETTER****FLA-03-12**

January 8, 2003

Ellsa G. Cabrera, President
Enka Products Company, Inc.
524 N.W. 57th Avenue
Miami, Florida 33128

Dear Ms. Cabrera:

This is in reference to "Anestenka" oral anesthetic products that your firm manufactures and distributes. Based on the labeling claims that the products are for use in the relief of toothache pains, denture irritation, and other conditions, they are drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Inspection of your firm revealed that "Anestenka" is manufactured in two formulations, one labeled in English and one labeled in Spanish. The formulation that is labeled in English contains benzocaine and propylene glycol. The product that is labeled in Spanish contains benzocaine, antipyrine, and propylene glycol. The Spanish-labeled product is intended for distribution to the Commonwealth of Puerto Rico and for export to foreign countries. Labeling for both products states that they are useful as topical anesthetics for toothache, denture irritation, and teething babies. Additional claims for the products include "temporary relief of cuticle pain, Hand nails (sic), minor cuts, Burns, Abrasions, ingrown nails."

Under final regulations found at Title 21, Code of Federal Regulations (21 CFR) part 310.545(a)(14), antipyrine is not permitted as an ingredient in OTC oral anesthetic drug products. Because antipyrine is not permitted in such drugs, we consider the "Anestenka" product labeled in Spanish to be a "new drug" [Section 201(p) of the FFDCA]. Under Section 505(a) of the FFDCA, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. Because your product is not the subject of an approved NDA, it may not be marketed in the United States and its continued distribution in interstate commerce violates Section 505 of the FFDCA. Distribution to Puerto Rico is distribution in interstate commerce and is not exportation. Distribution of your unapproved new drug into Puerto Rico is thus a violation of Section 505(a) of the FFDCA.

Exportation is also distribution in interstate commerce [Section 201(b)(1)]. However, unapproved new drugs can be legally exported to other countries if all of the requirements of the exemption provided by Section 802 of the FFDCA are met. You are not in compliance with Section 802 because your drugs are not manufactured in substantial conformity with current Good Manufacturing Practice requirements. You may also fail to meet other requirements of Section 802. For example, if your drug does not have approval in one of the countries listed in Section 802, it can only be exported to a non-listed country if FDA has made certain findings. Thus, your exports do not satisfy the Section 802 exemption and, therefore, they violate Section 505(a) of the FFDCA.

The "Anestenka" formulation that is labeled in English identifies the ingredients as benzocaine and propylene glycol without designating either as active or inactive. Thus, the product is misbranded under Section 502(a) of the FFDCA [see 21 CFR 201.10(c)(4)].

The "Anestenka" product labeled in English is also misbranded under Section 502(f)(1) of the FFDCA because it fails to bear any directions for use for the topical indications of "temporary relief for cuticle pain, Hand nails (sic), minor cuts, Burns, Abrasions, ingrown nails."

Both products are also misbranded under Section 502(a) and Section 502(c) and adulterated under Section 501(a)(2)(B) of the FFDCA in that the tamper-evident packaging statements, "DO NOT USE IF THE SEAL IS BROKEN" and "NO USAR SI EL SELLO ESTA ROTO," fail to identify the specific tamper-evidence feature used as required by 21 CFR 211.132.

The inspection revealed that both formulations of the drug are adulterated within the meaning of Section 501(a)(2)(B) of the FFDCA in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current Good Manufacturing Practice (GMP) regulations for drugs specified in 21 CFR 211, as follows:

Certificates of analysis from the component suppliers are not periodically tested for all required component specifications to verify the certificate of analysis results (21 CFR 211.84);

Expiration dates are not related to storage conditions as determined by stability studies, nor are storage conditions listed on the label. Further, the product bears a 30-month expiration date, which is not supported by shelf life studies demonstrating stability of the product over that period of time. Accelerated studies cannot be used to extend the expiration date beyond 2 years (21 CFR 211.137);

Failure to maintain adequate master production and control records in that test methods for raw material and finished product testing are not included (21 CFR 211.186);

Written procedures for equipment cleaning and maintenance are incomplete, and the cleaning procedure has not been properly validated (21 CFR 211.67); and

Failure to establish storage time limits for finished product in bulk container, in that 12 gallons of "Anestenka" had been stored in bulk 5-gallon containers for 10 months [21 CFR 211.100(b)].

We are in receipt of your response dated July 13, 2001, to our list of Inspectional Observations (FD-483). The response is inadequate in a number of aspects, including: all tests performed by the contract laboratory need to be documented; cleaning validation must confirm and document that no cleaning residuals remain; specifications and acceptance criteria for both raw materials and finished product are not included in the master production and control records; and, as stated above, accelerated studies can only be used to support a maximum expiration date of two years.

The above list of violations is not intended to be an all-inclusive list of deficiencies with products distributed by your firm. It is your responsibility to ensure that the drug products you distribute meet all the requirements of the FFDCA and its implementing regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for delay and the time frame within which corrections will be made.

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Your reply should be addressed to Martin E. Katz, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Emma R. Singleton
Director, Florida District