Subpart G - Packaging & Labelling Control

(21 CFR 211.122 – 211.137)

211.122 Materials examination and usage criteria.

211.125 Labeling issuance.

211.130 Packaging and labeling operations.

211.132 Tamper-evident packaging require ments for over-the-counter (OTC) human drug products.

211.134 Drug product inspection.

211.137 Expiration dating.

Your firm failed to assure that the drug product bore an expiration date that was supported by appropriate stability testing (21 CFR 211.137(a)).

Your response to our request for records and other information under section 704(a)(4) indicated that you did not perform stability testing. Therefore, you have not demonstrated that the active ingredient in your drug products is stable throughout its shelf life.

Without appropriate stability data, you cannot ensure your drug products meet established specifications and all pre-determined quality criteria throughout their assigned shelf-life.

Your firm failed to establish an adequate stability program and lacked chemical and microbial testing data to demonstrate that your over-the-counter (OTC) drug products will remain acceptable throughout their assigned expiry period.

You assigned U.S. marketed product expiration dates based on your domestic (China) product stability testing. However, the formulations and components for products intended for the U.S. market differed from your domestic product formulations.

In your response, you state you communicated with distributors of products marketed in the United States to request samples of each product for stability testing.

Your response is inadequate. You do not provide sufficient information regarding the batches, formulation, analytical method, and testing interval for the remaining expiry period. We acknowledge that you have not shipped product to the U.S. market since **(b)(4)**. However, your drug products in the U.S. market will expire by **(b)(4)**. For products without appropriate stability studies, you lack sufficient scientific evidence to support that the drug products will meet established specifications and retain their quality attributes throughout their labeled expiry. Please refer to 21 CFR 211.166, “Stability testing,” for the requirements of stability testing.

Your firm assigned a **(b)(4)** expiry period to your OTC topical pain relief product without scientific rationale to support the labeled expiry. At the time of inspection, you lacked stability data to support the **(b)(4)** expiry period. There was no assurance that your drug

product will remain acceptable throughout its labeled expiry period without an established stability program. During the inspection, you stated that your product's expiry is "anecdotal."

For products without appropriate stability studies, there is insufficient scientific evidence to support that the drug products will meet established specifications and retain their quality attributes through their assigned expiry.