



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

March 4, 2004

WARNING LETTER NYK 2004-08

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Kenneth J. Andersen, Ph.D.
Andersen Pharmaceuticals
5851 County Road 32
P.O. Box 848
Norwich, New York 13815

Dear Dr. Andersen:

An inspection of your manufacturing facility was performed on September 24-30, 2003, by U.S. Food and Drug Administration Investigators Steven J. Libal and Andrew M. Abramowitz. The inspection revealed that [REDACTED] Liquid Styptic, manufactured by your firm for [REDACTED] is an unapproved new drug and a misbranded drug that violates the Federal Food, Drug and Cosmetic Act (the Act), as described below.

Based on statements appearing on the immediate container label, such as "LIQUID STYPTIC," "TO STOP BLEEDING DAB-ON MINOR CUTS AND MANICURE NICKS," and "ANTISEPTIC," [REDACTED] is a drug as defined in section 201(g) of the Act. Because this product is intended to stop bleeding, it is an astringent drug and it must comply with the final over-the-counter (OTC) drug monograph under Title 21 of the Code of Federal Regulations, Part 347 (21 CFR 347), Subpart A, "SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE - Astringent Drug Products" (this final monograph was re-codified under 21 CFR 347, Subparts A, B, and C in the Federal Register of June 4, 2003 [68 FR 33362] See http://www.fda.gov/cder/otcmonographs/Skin_Protectant/skin_protectant_FM_20030604.pdf). All OTC astringent drug products marketed in the United States must be formulated and labeled in accordance with this final monograph to be generally recognized as safe and effective and not misbranded. Your product fails to comply with the final monograph, as follows:

- The label for [REDACTED] does not distinguish between active and inactive ingredients. This causes all of the labeled ingredients (i.e., aluminum chloride, urea, benzocaine, methylene blue, menthol, and alcohol) to be represented as active ingredients. OTC astringent drug products intended to stop bleeding caused by minor surface cuts and abrasions may contain only aluminum sulfate as the active ingredient and this ingredient may only be offered in a styptic pencil form. See 21 CFR § 347.10(b) and § 347.50(b)(2) (re-codified as 21 CFR § 347.12(b) and § 347.52(b)(2), respectively). [REDACTED] does not contain aluminum sulfate as the sole active ingredient and it is not offered in a styptic pencil form.

- The final monograph has no provisions for labeling OTC astringent drug products with claims for topical antiseptic use.
- [REDACTED] does not bear any warnings required to appear on the labeling for OTC astringent drug products, including, "Warning: For external use only. Avoid contact with the eyes." See 21 CFR § 347.50(c)(1) (re-codified as 21 CFR § 347.52(c)(1)).
- This product is not labeled with a statement of identity, as required by 21 CFR § 347.50(a) (re-codified as 21 CFR § 347.52(a)).

Because [REDACTED] fails to comply with the final OTC drug monograph for astringent drug products, as described above, and it is not generally recognized as safe and effective, this product is a "new drug" within the meaning of section 201(p) of the Act. Since this product is not the subject of an approved new drug application (NDA), its marketing in the United States violates section 505(a) of the Act.

The failure of the labeling for this product to bear a statement of identity and warnings, as required by the final monograph and as noted above, causes it to be misbranded under sections 502(a) and 502(f)(2) of the Act, respectively. To be legally marketed in the United States, the product would have to be reformulated and relabeled to meet the requirements of 21 CFR Part 347, or approved under the NDA provisions of the Act.

In addition, the labeling for [REDACTED] fails to comply with the regulations under 21 CFR § 201.66 covering the format and content of OTC drug labeling. See <http://www.fda.gov/cder/Offices/OTC/DrugFactsFinalRule.pdf>. These regulations establish the criteria for ensuring that OTC drug labeling information is conspicuous at the time of purchase and use. The failure to comply with these criteria misbrands this product under section 502(c) of the Act.

[REDACTED] is also misbranded under section 502(e)(1)(A)(ii) of the Act because the quantity, kind, and proportion of alcohol contained in it are not disclosed on the label. Further, the product's label does not list all of its inactive ingredients. In this regard, the presence of water in the formulation is not disclosed. Therefore, the product is misbranded under section 502(e)(1)(A)(iii) of the Act.

Since your drug manufacturing facility is not registered in accordance with Section 510 of the Act, as described in 21 CFR Part 207, [REDACTED] is further misbranded under section 502(o) of the Act.

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act. Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs and devices so that they may take this information into account when considering the award of contracts. We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

The inspection of your facility also revealed violations of current good manufacturing practice (CGMP) regulations (21 CFR Parts 210 and 211) which would cause [REDACTED] to be adulterated within the meaning of section 501(a)(2)(B) of the Act. These CGMP deficiencies include:

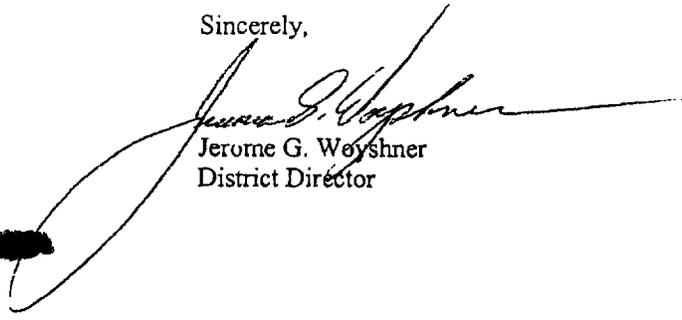
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- Actual yield and percentages of theoretical yield are not determined at the end of each appropriate phase of packaging [21 CFR § 211.103]. For example, correct percentage yields are not recorded in the batch records for some lots of this product.
- Batch production and control records lack the weight and measures of components used in the processing of each batch [21 CFR § 211.188(b)]. For example, five out of six batch records examined did not document the actual quantities of ingredients added.
- Batch production and control records lack an accurate reproduction of the appropriate master production and control record that has been checked for accuracy, dated and signed [21 CFR § 211.188(a)]. For example, the quantity (Weight) of SDA alcohol specified in the current master batch record differs from that specified in the current batch record form used in production
- There was evidence of failure to follow written procedures for production and process control in the execution of all production and process control functions in that all manufacturing vessels do not bear a status tag, as required by SOP# AL 002C [21 CFR § 211.100(b)].
- There was evidence of failure to investigate unexplained discrepancies in batch production records [21 CFR § 211.192]. For example, no investigation was conducted into failures of batches to meet your firm's specification for maximum yield.

Please send a written response to this office within fifteen working days of receipt of this letter. Your response should describe the specific actions that you will take, or have taken, to correct the violations described in this letter. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed. Direct your response to James M. Kewley, Compliance Officer, at the above address.

Sincerely,


Jerome G. Weyshner
District Director

cc:

