DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

February 26, 2007

President and/or CEO
SDA Laboratories Inc.
280 Railroad Avenue
Greenwich, Connecticut 06830

Dear Mr. or Ms. President and/or CEO:

This letter is written in reference to the marketing by your firm of Ergocaff PB Suppositories, a drug product containing ergotamine tartrate.

Drug products containing ergotamine that were marketed under new drug applications approved for safety only prior to 1962 were reviewed under the Drug Efficacy Study Implementation (DESI) program. On July 27, 1972, the Agency concluded that such products are new drugs effective for the treatment or prevention of "vascular headaches" ("e.g. migraine, migraine variants or 'histaminic cephalalgia'") subject to section 505 of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 355] and that approved new drug applications are required to market them. (37 Fed. Reg. 15032).

Under 21 C.F.R. § 310.6(b)(1), the ergotamine-containing product that you market is identical, related, or similar to the drugs reviewed in this DESI proceeding. Under 21 C.F.R. § 310.6(b)(2), the "new drug" determination made under this DESI proceeding applies to your product and therefore your product requires an approved new drug application before it may be lawfully sold. As there is no approved new drug application on file with the FDA for Ergocaff PB Suppositories as marketed by your firm, the marketing of this product is in violation of sections 301(d) and 505(a) of the Act, [21 U.S.C. §§ 331(d) and 355(a)], which prohibit the introduction or delivery for introduction into interstate commerce of a new drug without an approved new drug application.

Moreover, Ergocaff PB Suppositories is a prescription drug within the meaning of section 503(b)(1) of the Act, [21 U.S.C. § 353(b)(1)], because it is not safe for use except under the supervision of a practitioner licensed by law to administer such drug. By definition, a prescription drug's directions for use are not adequate to enable a layperson to safely use the drug for its intended uses. See 21 C.F.R. § 201.5. Consequently, Ergocaff PB Suppositories labeling fails to bear adequate directions for use under section 502(f)(1) of the Act, [21 U.S.C. § 352(f)(1)]. Because it lacks an approved application, it is not exempt from this requirement under 21 C.F.R. § 201.115. Ergocaff PB Suppositories is therefore misbranded.

In general, unapproved drugs are a public health risk because they may not meet modern standards for safety, effectiveness, quality, and labeling. Even though some ergotamine products were found to be effective for certain indications via the DESI process, this does not necessarily mean that Ergocaff PB Suppositories as currently formulated, manufactured, and labeled, is effective or safe.

The above identified violations are not intended to be an all inclusive list of violations involving your facility. It is your responsibility to assure that your firm is in compliance with all requirements of the Act. We request that you review all drug products that you are currently marketing to assure they are

in compliance with the Act and FDA regulations. If you no longer market any ergotamine-containing drug products or believe that you have received this letter in error, please notify the Agency at the address below.

As described in the guidance entitled "Marketed Unapproved Drugs – Compliance Policy Guide" ("Marketed Unapproved Drugs CPG"), the Agency may exercise its enforcement discretion and identify a period of time during which the Agency does not intend to initiate an enforcement action against a currently marketed unapproved drug. http://www.fda.gov/cder/guidance/6911fnl.pdf. The Agency intends to exercise its enforcement discretion with regard to unapproved, ergotamine-containing drug products as follows. FDA does not intend to initiate enforcement actions related to currently manufactured unapproved ergotamine-containing products if those products are listed with FDA under section 510 of the Act, [21 U.S.C. § 360], as of the date of this letter, unless the manufacturing of those products continues after April 27, 2007. Further, FDA does not intend to initiate enforcement actions related to the shipment in interstate commerce of unapproved ergotamine-containing products made by such firms, including Ergocaff PB Suppositories, unless they are still being shipped on or after August 25, 2007[1].

You should be aware that the Agency does not intend to exercise its enforcement discretion as described in this letter in the following circumstances: (1) if a firm is violating other provisions of the Act; (2) when it appears that a firm, in response to this letter, increases its manufacture or distribution of unapproved ergotamine drug products above its usual volume during these periods; (3) if FDA learns of new information regarding any serious health risk or hazards associated with an unapproved ergotamine drug product; or (4) if a firm marketing unapproved ergotamine products does not undertake appropriate corrective action to cease marketing the products.

To avail your firm of these periods during which the Agency intends to exercise enforcement discretion regarding unapproved ergotamine products, you must reply within fifteen (15) days of your receipt of this letter with a commitment to comply with the conditions stated above. Please include:

- a statement(s) of what action you plan to take to comply;
- a statement of the amount of Ergocaff PB Suppositories, and any other unapproved ergotamine-containing product, that is (are) in inventory under your control;
- the time period in which you expect such inventory to be exhausted, in its entirety, and your plan for disposition of any inventory remaining after the above shipment cessation date; and
- an estimate of when products in distribution channels will become exhausted.

If FDA receives your commitment within fifteen (15) days of your receipt of this letter, the agency intends to exercise its enforcement discretion as described above, unless the circumstances listed above or lack of compliance with the conditions set forth in this letter warrant further action. If FDA does not receive a commitment within fifteen (15) days of receipt of this letter or a firm or person fails to comply with the stop manufacture or stop shipment date, the agency may take immediate regulatory action, including but not limited to seizure and/or injunction. If FDA takes action, to preserve limited agency resources, FDA may also take simultaneous enforcement action relating to any other unapproved new drugs manufactured, distributed, or shipped by the defendant. (*See, e.g., United*

[1] The agency intends to take enforcement action against unapproved ergotamine-containing products and those who cause them to be manufactured or shipped in interstate commerce (whether or not they have received a warning letter from FDA) after these dates.

States v. Sage Pharmaceuticals, 210 F.3d 475, 479-480 (5th Cir. 2000) (the agency can combine all violations of the act in one proceeding, rather than taking action against a firm with multiple violations of the act in "piecemeal fashion").)

In addition, FDA cautions firms against reformulating their products into ergotamine-free unapproved new drugs that are marketed under the same name or substantially the same name (including a new name that contains the old name). In the Marketed Unapproved Drugs CPG, FDA states that it intends to give higher priority to enforcement actions involving unapproved drugs that are reformulated to evade an FDA enforcement action. In addition, reformulated products marketed under a name previously identified with a different active ingredient or combination of active ingredients have the potential to confuse health care practitioners and harm patients.

Please send your reply via fax, as well as mail or overnight delivery to: Valerie L. Whipp, U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Division of New Drugs and Labeling Compliance, 11919 Rockville Pike, HFD-310, Rockville, MD 20852, fax number (301) 827-8904.

For information regarding the drug approval process see www.fda.gov/cder/regulatory/applications/default.htm. Should you wish to seek approval for your ergotamine product, you may contact Sally Loewke, MD, the Agency's unapproved drugs coordinator at (301) 796-0710, who can help you identify the appropriate review division or office for further direction. However, until such time as you have FDA approval for your product, you must comply with this letter.

Sincerely yours,

Michael Levy
Director
Division of New Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research