DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

# WARNING LETTER

**CERTIFIED MAIL-
RETURN RECEIPT REQUESTED**

OCT 29 2008

Russell Reitz, CEO/President
Aerosol Science Laboratories Inc.
900 Calle Plano, Suite M
Camarillo, CA 93012

Dear Mr. Reitz:

We recently reviewed your firm's website, www.aslrx.com. As explained below, your website contains false and misleading claims for your firm's compounded aerosolized medications that are used with the SINUS SCIENCE Aerosol Medication Delivery System, causing these drugs to be misbranded in violation of Section 502(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 USC § 352(a)].

## A. Misbranded Drugs Under Section 502(a) of the FDCA

Under section 502(a) of the FDCA, a drug is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FDCA [21 U.S.C. § 321(n)] provides that, in determining whether a drug's labeling or advertising "is misleading, there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising . . . fails to reveal facts material in light of such representations . . . ."

Compounded nasally inhaled products promoted on your website include antibiotics, anti-fungals, anti-inflammatories and mucolytics for the treatment of allergic rhinitis, chronic sinusitis, sinus headaches, and loss of smell. These compounded drug products are misbranded within the meaning of sections 502(a) and 502(f)(1) of the FDCA for the following reasons:

### *1. Unsubstantiated Efficacy Claims*

Your firm's website contains claims concerning your firm's compounded aerosolized medications that are used with the SINUS SCIENCE Aerosol Medication Delivery System, including:

- "Chronic Sinusitis and Allergic Rhinitis may affect how you feel, taste, smell and breathe, but aerosolized treatment should help you experience an improvement in these symptoms."

FDA regards these claims as false or misleading under section 502(a) of the FDCA. FDA is not aware of substantial evidence (consisting of adequate and well controlled clinical investigations) that supports these claims.

Further, your firm's website contains the following statements:

- "Inhaled antibiotics, anti-fungals, anti-inflammatories and mucolytics are new treatment choices for allergic rhinitis, chronic sinusitis, sinus headaches and loss of smell."

This statement is false or misleading under section 502(a) of the FDCA. Your website claims that the drug classes listed – antibiotics, anti-fungals, anti-inflammatories, and mucolytics – are, by the nasal inhalational route, a new treatment of acute or chronic sinusitis, sinus headaches, or loss of smell. The inhalation forms of these products have not been approved for the treatment of chronic sinusitis, allergic rhinitis, sinus headaches or loss of smell.

In addition, we note that the labeling fails to bear adequate directions for use for these claims under section 502(f)(1) of the FDCA.

*2. Unsubstantiated Superiority Claims*

Your website includes statements about the compounded drugs used with the SINUS SCIENCE Aerosol Delivery System indicating that the fine particles produced by the system provide better therapeutic benefit than nasally inhaled products from nasal spray bottles. Such statements include, "Typical spray bottles produce large droplets of up to 150 microns in diameter, most of which end up clinging to the walls of the nasal cavity, failing to reach into the sinuses" and "These tiny particles are only about 3.1 microns in diameter so they can get to places where the large droplets produced by spray bottles will not reach."

These statements represent that your firm's inhaled antibiotics are superior to other products, including FDA-approved drugs. These claims – which are unsupported by substantial evidence (consisting of adequate and well controlled clinical investigations) – are false or misleading under section 502(a) of the FDCA. In addition, we note that the labeling fails to bear adequate directions for use for these claims under section 502(f)(1) of the FDCA.

Furthermore, the droplet size characteristics described for the SINUS SCIENCE Aerosol Medication Delivery System actually raise safety and efficacy concerns. One important consideration when developing products for nasal delivery is the aerodynamic particle or droplet size. Particles or droplets that are aerodynamically smaller than 5 microns can be inhaled into the lungs, and pulmonary inhalation of products intended for nasal delivery may have potential safety concerns. Furthermore, the aerodynamic characteristics of the formulation generated by

the delivery system should be such that the drug product will be retained in the nasal cavity. If the product is not retained in the nasal cavity, efficacy could be an issue.[1]

As explained above, the claims made for your compounded drugs that are used with the SINUS SCIENCE Aerosol Delivery System are false or misleading under section 502(a) of the FDCA. These claims cause your drugs to be misbranded under sections 502(a) and 502(f)(1) of the FDCA.

**B. SINUS SCIENCE Aerosolizing Device**

We also note that our records contain no evidence of clearance or approval of the SINUS SCIENCE™ aerosolizing device, either as a device on its own under sections 510(k) or 515(a) of the FDCA or as a constituent part of a combination product. Absent either clearance or approval, your product is in violation of the FDCA and should not be marketed. Please contact Mr. Michael Husband in FDA's Center for Devices and Radiological Health, Anesthesiology Devices Branch at 240-276-3775 for marketing requirements of the delivery system (medical device alone) for general use with drugs already approved for these indications and route of delivery. The CDRH website link for general information is http://www.fda.gov/cdrh/devadvice/.

**C. Conclusion**

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist on your website, and they may not be limited to the above-cited drug products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence and the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the cited violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

If you have any questions or need clarification regarding this letter prior to your written response, you may contact Lisa Tung, Compliance Officer at telephone number 301-796-3305. Your written response should be directed to:

---

[1] *See Guidance for Industry: Sinusitis: Designing Clinical Development Programs of Nonantimicrobial Drugs for Treatment,* available at http://www.fda.gov/cder/Guidance/7316dft.htm.

Michael M. Levy Jr.
Director, Division of New Drug and Labeling Compliance
Office of Compliance
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building 51, Room 5188
Silver Spring, MD 20993

Sincerely,

Kathleen R Anderson for

Michael M. Levy, Jr.