



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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By Certified Mail - Return Receipt Requested

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville MD 20852-1448

JUL 24 2001

Warning Letter

Marilyn A. Coleman, Ph.D., President
OvImmune
2532 Zollinger Road
Columbus, Ohio 43221

CBER - 01 - 022

Dear Dr. Coleman:

This letter is in reference to your distribution and promotion of eggs containing antibodies produced by immunization of chickens with investigational vaccines.

From available documents and an interview between you and Food and Drug Administration (FDA) investigator Hugh McClure held on March 23, 2001, FDA determined that you provided to human subjects eggs containing antibodies produced by immunization of chickens with investigational vaccines in violation of the Public Health Service Act (PHS Act) and the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The eggs containing antibodies produced by immunization of chickens with investigational vaccines are biological products as defined in Section 351(i) of the PHS Act (as amended November 21, 1997), in that they are biological products applicable to the prevention, treatment, or cure of diseases or injuries to human beings, and are subject to Section 351(a) of the PHS Act. Eggs containing antibodies produced by immunization of chickens with investigational vaccines also are drugs within the meaning of Section 201(g) of the FD&C Act in that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man.

Section 351(a) of the PHS Act is being violated in that unlicensed biological products (eggs containing antibodies produced by immunization of chickens with investigational vaccines) are being introduced or delivered for introduction into interstate commerce with no approved biologics license application (BLA) in effect, nor any investigational new drug application (IND) in effect pursuant to Section 505(i) of the FD&C Act.

The eggs containing antibodies produced by immunization of chickens with investigational vaccines are misbranded under Section 502(f)(1) of the FD&C Act because the labeling fails to bear adequate directions for use. Adequate directions cannot be written for unapproved drugs.

Your firm's website at <http://www.ovimmune.com> is promoting your firm's egg products and contains the following examples of therapeutic claims about your firm's eggs containing antibodies produced by immunization of chickens with investigational vaccines:

"Now specially produced eggs can replace the immunity lost during these diseases [AIDS, transplant, burn, cancer] and ameliorate the effects of routine infections."

..using egg antibodies to potentially treat all known diseases.

"By hyper-immunizing hens against opportunistic organisms, IgY can be used to replace failing secretory IgA and protect the mucosa from adhesion of enteric pathogens...."

"We can produce true 'magic bullets' that can be attached to a lethal agent to target and destroy unwanted biologic entities such as cancer."

Furthermore, the following statement is incorrect for the reasons cited in this letter and should be removed: "... (OvImmune) has been given GRAS (generally regarded as safe) status from ... FDA for the use of egg antibody in human patients..." Readers may misinterpret this statement since it implies that the FDA reviewed and has permitted the research of your firm's investigational eggs for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man.

This letter is not intended to be an all-inclusive list of deficiencies observed at your facility. It is your responsibility to ensure adherence to each requirement of the FD&C Act, PHS Act, and relevant regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing, within fifteen (15) business days of receipt of this letter of the specific steps you have taken to correct the noted violations. Corrective actions include, but are not limited to, discontinuing administration of eggs containing antibodies produced by immunization of chickens with investigational vaccines to human subjects, revision to your firm's website, and the submission of an IND.

Eggs containing antibodies produced by immunization of chickens with investigational vaccines may only be studied as drugs in the United States if there is an IND in effect. You may submit an IND application to the FDA pursuant to Title 21, Code of Federal Regulations Part 312 (21 CFR Part 312). If an IND is submitted, no clinical

investigation is permitted to proceed until the IND is in effect, as described in 21 CFR §§ 312.20 and 312.40. These regulations are available at <http://www.access.gpo.gov/nara/cfr/index.html>.

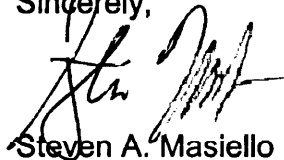
Information to assist you in submitting an IND application is available at <http://www.fda.gov/cber/ind/ind.htm>. Questions regarding submission of an IND application and assistance may be directed to the Office of Communications, Training, and Manufacturers Assistance at (800) 835-4709.

Your response to this letter should be sent to the following address:

Patricia Holobaugh (HFM-664)
Division of Inspections and Surveillance
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448
Telephone (301) 827-6221

We request that you send a copy of your response to the Food and Drug Administration's Cincinnati District Office at the address listed below.

Sincerely,



Steven A. Masiello
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

cc: Henry Fielden, Director
Food and Drug Administration
6751 Steger Drive
Cincinnati, Ohio 45237-3097