August 26, 2011

Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Citizen Petition to Issue Warning Letter to Boiron Concerning Its Misleading Marketing of Oscillococcinum on Its Website

The undersigned submit this petition on behalf of the Center for Inquiry ("CFI") and its affiliate, the Committee for Skeptical Inquiry ("CSI"), pursuant to Section 502(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 352(a) ("the Act"), which provides the Federal Food and Drug Administration ("FDA" or "Agency") with the authority to take appropriate action in the event a drug is misbranded.

CSI is a nonprofit organization dedicated to promoting scientific inquiry and critical investigation, including critical investigation of claims relating to unconventional healthcare practices, such as homeopathic medicine. CSI’s advisors include a number of leading scientists, many of whom are medical specialists. See http://www.csicop.org/about/csi_fellows_and_staff/. CFI is a nonprofit organization supporting the activities of CSI, among other organizations.

A. Action requested

The undersigned hereby request the Commissioner of Food and Drugs to issue a warning letter to Boiron, the manufacturer of Oscillococcinum, a homeopathic drug, for misleading advertising, and to direct Boiron to cease immediately its misleading promotional activities.

B. Statement of grounds

This Agency has the authority to require drug manufacturers to refrain from false or misleading advertising of their product, pursuant to Section 502(a) of the Act. A product is illegally misbranded if its labeling is false or misleading “in any particular.”
Boiron maintains a website which displays a package of Oscillococcinum. See Exhibit A and http://www.oscillo.com/about/facts-about-oscillo. Immediately adjoining the package is a set of “FACTS ABOUT OSCILLOCOCCINUM.” The purported facts tell consumers, in pertinent part, that: “Four clinical studies... show that Oscillo reduces the severity and duration of flu-like symptoms .... As with all Boiron homeopathic medicines, Oscillo complies with a well-established framework of guidelines, regulations and quality standards enforced by the FDA through routine pharmaceutical manufacturing site inspections and surveillance on marketed products.”

In context, Boiron’s promotional claims imply that Oscillococcinum has received FDA approval through FDA-supervised testing of its efficacy. This is, of course, not true. Boiron’s claims—which given the configuration of the ad can be said to constitute an integral part of the “labeling” of its product—are materially misleading.

C. Environmental impact

Nothing requested in this petition will have an impact on the environment.

D. Economic impact

The only potential loss of income that might result from the requested action is to Boiron, the manufacturer of Oscillococcinum. There would be savings to consumers who would not purchase the product were Boiron’s advertisements not misleading.

E. Certification

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the undersigned which are unfavorable to the petition.

Ronald A. Lindsay, President & CEO
Center for Inquiry
3965 Rensch Road
Amherst, NY 14226
(716) 636-4869 ext. 215

Barry Karr, Executive Director
Committee for Skeptical Inquiry
3965 Rensch Road
Amherst, NY 14226
(716) 636-4869 ext. 217
FACTS ABOUT OSCILLOCOCCINUM

Oscillococcinum has been used for centuries by practitioners in France and has been studied for more than 50 years. For the first time, a medicine, prepared by pharmacists, using a homeopathic record of safety and efficacy, can be marketed in the United States. This remedy is the result of a strict selection process for safety, efficacy, and quality, conducted by the US Food and Drug Administration (FDA). The remedy is manufactured by Boiron in France, using a homeopathic protocol that ensures the potency of the remedy.

HOMEOPATHIC REMEDY

Oscillococcinum is a homeopathic remedy used for the relief of symptoms associated with influenza-like illness. It is indicated for the relief of symptoms such as fever, chills, body aches, and fatigue.

How to Use

Take 2 tablets when symptoms first appear and again every 4 hours, up to 8 times a day. Do not exceed 32 tablets per day.

PRECAUTIONS

Consult a doctor before use in children under 2 years of age, children with a history of seizure disorder, or those who are pregnant or nursing.

Active Ingredients

- Arsenicum album 3C XN - To reduce fever and relieve body aches
- Aconitum napellus 3C XN - To relieve chills and fever
- Bellis perennis 3C XN - To relieve runny nose and sneezing
- Nux vomica 3C XN - To relieve nausea and vomiting

Inactive Ingredients

- Lactose, sucrose, microcrystalline cellulose

WARNING

Do not use if plaques/capsules are open or if tablets stick together. Do not use if you are pregnant or breastfeeding. If you develop chest pain, severe diarrhea, or fever, discontinue use and consult a doctor. Contact your doctor immediately if you have any of the following symptoms: chest pain, shortness of breath, severe diarrhea, or fever.

Additional Information

Keep out of reach of children. Store at 59°F (15°C). If you have any questions, please call our customer service at 1-800-222-5488.

About Boiron

Boiron is a world leader in natural medicine, with over 30 years of experience in homeopathic research and development. Our remedies are manufactured using the highest quality standards and are scientifically evaluated by independent researchers. Boiron is committed to providing safe, effective, and affordable remedies to people worldwide.

Exhibit A