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.

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FACTS ABOUT OSCILLOCOCCINUM

Manufactured by Boiron, Oscillococcinum has a long history of safety and efficacy. Oscillococcinum is used by millions of patients in more than 100 countries. In France, Oscillococcinum has been approved by the Ministry of Health since 1983. It is recommended in the 2017 French National Health Guide for use in the management of influenza-like symptoms. It is taken at the first sign of symptoms, under the guidance of a healthcare professional:

- Fever
- Body aches
- Headache
- Fatigue

Use in children under 2 years of age is not recommended.

DOSAGE is available in 1, 6 or 12 doses. Adults and children 2 years and older: Shake well before use. Use every 2 hours, up to 3 times a day.

ACTIVE INGREDIENTS:
- Aqueous extract of Vibrio parahaemolyticus B100 1:1000 – To reduce the duration and severity of flu-like symptoms

Other information:
- Store at room temperature (15°C to 30°C), away from direct sunlight.
- Keep out of reach of children.
- For more information or comments on Oscillococcinum, please contact Boiron Information Center at 1-888-629-9959.