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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

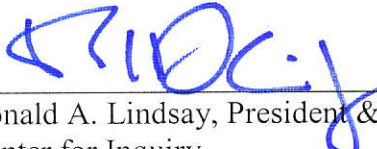
Nothing requested in this petition will have an impact on the environment.

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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Exhibit A
 Boiron Oscillocochinum Product Web Page,
<http://www.oscillo.com/about/facts-about-oscillo/>

BOIRON
Home | Products | Locations | Healthcare Professionals



Oscillocochinum

HOMOEOPATHIC MEDICINE FOR HEADACHE, BODY ACHES, CHILLS & FEVER



U.S. FDA APPROVED
 PRODUCT
 FOR
 HEADACHE

About Oscillo
Cough, Cold & Flu
Press Room
Special Offers
Testimonials
Healthcare Professionals

FACTS ABOUT OSCILLOCOCHINUM

Like 67
Follow 3
Post 3

Manufactured by Boiron, Oscillocochinum has a long history of efficacy and safety. Oscillo is used by millions of patients in more than 60 countries. In France, where Oscillo has been used for more than 65 years, it is the first flu medicine recommended by pharmacists. It has a remarkable record of safety and can be recommended to patients over age 2 and those who are following other treatments or suffering from chronic conditions. Oscillo will not cause drug interactions or side effects. Four clinical studies, including two which have been published in peer-reviewed journals, show that Oscillo reduces the severity and duration of flu-like symptoms such as feeling run down, headache, body aches, chills and fever. 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.

Uses:
 Temporarily relieves flu-like symptoms such as feeling run down, headache, body aches, chills and fever.

Directions:
 Adults and children 2 years of age and older: Dissolve entire contents of one tube in the mouth every 6 hours, up to 3 times a day.
 Children younger than 2 years of age: Ask a doctor before use.

Oscillo is available in 3, 6 or 12 doses. Also try Children's Oscillocochinum.

Check out our product locator to find the store nearest you.

Active ingredient:

- *Anas barbivix hepatitis vis cordis extractum 200CK-HPUS* - To reduce the duration and severity of flu-like symptoms.

The letters "HPUS" indicate that the active ingredients are officially included in the Homeopathic Pharmacopoeia of the United States.

Inactive ingredients:

- lactose, sucrose

Warnings:

- Do not use if glued carton end flaps are open or if the tray seal is broken.
- Ask a doctor before use in children younger than 2 years of age.
- Stop use and ask a doctor if symptoms persist for more than 3 days or worsen.
- If pregnant or breast-feeding, ask a health professional before use.
- Keep out of reach of children.

Other information:

- Store at 68-77°F (20-25°C).
- Each 0.04 oz. dose (1 g) of Oscillo contains 1 g of sugar.

For more information or comments on Oscillo, please contact:

Boiron Information Center
 6 Campus Boulevard
 Newtown Square, PA 19073-3267
 1-800-BOIRON-1 (1-800-264-7661)
info@boiron.com


RELATED SITES

- Oscillocochinum
- Children's Oscillo
- Chezar
- Aurizate
- Chakra Teaching
- Boiron USA

SITEMAP

- Home
- About Oscillo
- Cough, Cold & Flu
- Press Room
- Special Offers
- Testimonials
- Healthcare Professionals

THE BOIRON WAY



Watch the video to learn more about us.

ABOUT BOIRON

At Boiron, we believe there's a better way to feel good. A better way that works naturally with your body. Since 1832, the Boiron family has been committed to providing safe, natural medicines. As world leader in homeopathic medicines, our mission is your best health. Our purpose is your total satisfaction. Find out more at www.boironusa.com.

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