



P.O. Box 741 • Amherst, New York 14226-0741 • (716) 636-4869 • Fax (716) 636-1733
www.centerforinquiry.net

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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 Require English Language Labeling on
Boiron Oscillococcinum Drug Packaging and Website**

The undersigned submit this petition under Section 502(c) of the Federal Food, Drug, and Cosmetic Act (“the Act”) to request the Commissioner of Food and Drugs to issue a warning letter to Boiron USA (“Boiron”) requiring the company to label the contents of its homeopathic flu treatment drug product, “Boiron Oscillococcinum,” in English, pursuant to Section 502(c) of the Act and 21 C.F.R. § 201.15(c)(1).

A. Action requested

The undersigned hereby request the Commissioner of Food and Drugs to issue a warning letter to Boiron requiring the producer to list the ingredients of Boiron’s homeopathic drug product, “Boiron Oscillococcinum,” in plain English on the product label and on Boiron’s website. The undersigned further request that the Commissioner take appropriate measures in the event that Boiron fails to comply with this requirement.

B. Statement of grounds

Section 502(c) of the Act and its implementing regulation, 21 C.F.R. § 201.15(c)(1), together require that under normal circumstances, all words, statements, and other information required to appear on product labeling shall appear in the English language.

Section 502(c) of the Act requires that information required to appear on product labels must be displayed in such a manner “as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.” The Section’s implementing regulation, 21 C.F.R. § 201.15(c)(1), explicitly forbids the use of non-English language labeling, except under certain circumstances that do not obtain in this instance. Specifically, it provides that required information on product labels “shall appear thereon in the English language” (provided, however that “articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.”). 21 C.F.R. § 201.15(c)(1).

In addition, the Food and Drug Administration’s Compliance Policy Guide Sec. 400.400, “Conditions Under Which Homeopathic Drugs May be Marketed,” states explicitly that pursuant to Section 502(c) of

the Act and 21 C.F.R. § 201.15(c)(1), “the industry is required to translate these names [of homeopathic ingredients] from Latin to their common English names as current labeling stocks are depleted, or by June 11, 1990, whichever occurs first.”

Boiron’s package labeling for its homeopathic flu remedy, Boiron Oscillocoquinum, lists the product’s alleged active ingredient in Latin, “Anas barbariae hepatis et cordis extractum” rather than the English translation: “extract of Muscovy Duck liver and heart”. A copy of the product’s package labeling is attached hereto as Exhibit A. Boiron also lists Boiron Oscillocoquinum’s alleged active ingredient solely in Latin on the product’s website, <http://www.oscillo.com/about/facts-about-oscillo/>, a copy of which is attached hereto as Exhibit B.

By failing to list the product’s alleged active ingredient in the English language, Boiron is in violation of Section 502(c) of the Act and 21 C.F.R. § 201.15(c)(1).

The ordinary consumer is highly unlikely to understand Boiron’s obscure Latin description of the product’s alleged active ingredient. Among other confusions that may result from Boiron’s use of Latin, some consumers may be led to purchase Boiron Oscillocoquinum on the mistaken belief that its alleged active ingredient consists not of mere extract of duck liver and heart, but of other medication that has been scientifically proven to treat the flu and flu-like symptoms.

Requiring Boiron to comply with Section 502(c) of the Act and its implementing regulation will help ensure that customers make informed decisions when determining whether to purchase Boiron Oscillocoquinum. The undersigned urge the Commissioner to issue a warning letter to Boiron advising the company that it must list the product’s ingredients in plain English on the product’s packaging and on Boiron’s website. The undersigned further request that the Commissioner take appropriate measures in the event that Boiron should fail to comply.

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 the manufacturers and distributors of Boiron Oscillocoquinum. There would be savings to consumers who would not purchase the product if it were properly labeled.

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

Exhibit A

Photo of Ingredient Listing on Boiron Oscillococcinum Product Label

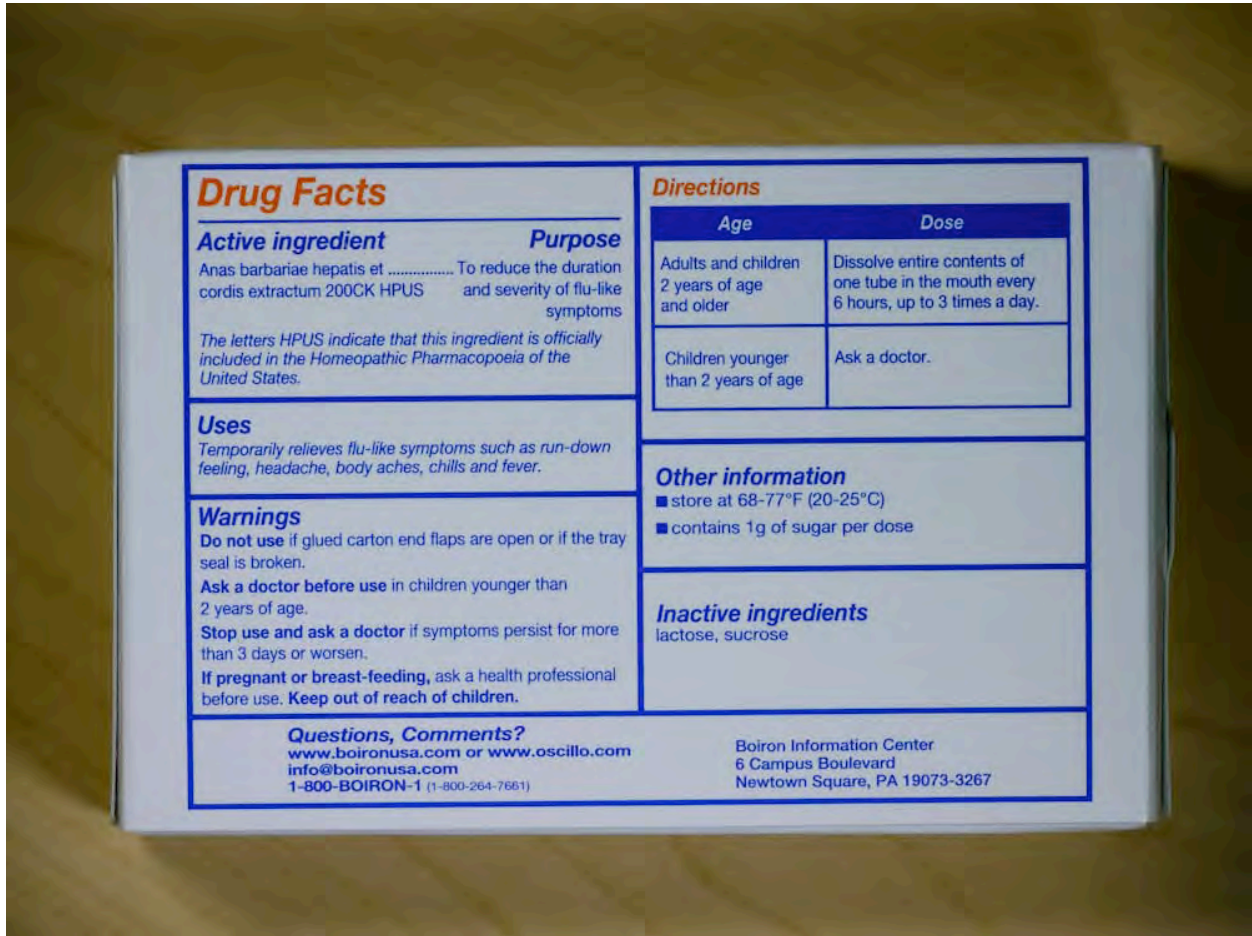


Exhibit B
Boiron Oscillocochinum Product Web Page,
<http://www.oscillo.com/about/facts-about-oscillo/>

BOIRON
 The like symptoms
Oscillocochinum
 HOMEOPATHIC MEDICINE FOR HEADACHE, BODY ACHES, CHILLS & FEVER

FACTS ABOUT OSCILLOCOCHINUM

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 barbariae hepatis et 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 Chestal
- Chestal
- Arnicare
- Camille Teeming
- 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 1932, the Boiron family has been committed to providing safe, natural medicines. As world leader in homeopathic medicines, our passion is your total health. Our promise is your total satisfaction. Find out more at www.boironusa.com.

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