DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 25 2007

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Ms. Mary G. Poff McDole
10535 E. Washington Street
PMB 229
Indianapolis, IN 46229

Re: Docket No. 2006P-0484/CP1

Dear Ms. Poff McDole:

This responds to your citizen petition dated November 21, 2006, requesting that changes be made to the labeling of stimulant medications such as Adderall (amphetamine-dextroamphetamine), Concerta (methylphenidate), and Ritalin (methylphenidate), used to treat attention deficit hyperactivity disorder (ADHD).

Specifically, you request that labeling include a statement to the effect that these medications should only be used "as a last resort in children (or people prior to having children)." Your requested labeling would also inform consumers that there is no information as to the long-term effects of these drugs.

As grounds for your petition, you cite a lack of information on the long-term effects of ADHD drugs on the stomach, kidneys, lungs, heart, brain, circulatory system, and reproduction. Your petition cites an unnamed speaker but does not otherwise provide any references to support your request. Because you have not provided adequate support for your request, your petition is denied.

Nevertheless, we acknowledge your concerns regarding stimulant medications and can advise you that in May 2006, as part of the U.S. Food and Drug Administration's (FDA or Agency) ongoing regulatory activity, the Agency directed manufacturers of this class of products to revise product labeling for doctors to reflect concerns about adverse cardiovascular and psychiatric events. These changes were based on recommendations from the FDA Pediatric Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

To help patients understand the risks of ADHD drugs, FDA announced in February 2007 that it had directed manufacturers of all drug products approved for the treatment of ADHD to develop patient medication guides to alert patients to possible cardiovascular

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risks and risks of adverse psychiatric symptoms associated with the medicines, and to advise them of precautions that can be taken. Medication guides are an additional part of the revised labeling process intended to provide patients with easy-to-understand information about a particular drug product when FDA determines that it is necessary to patients' safe and effective use of the drug product. More information regarding the patient medication guides for the identified drug products that treat ADHD,[1] as well as the revised professional labeling, is available at the FDA's website at http://www.fda.gov/cder/drug/infopage/ADHD/default.htm.

In general, FDA recommends that children, adolescents, or adults who are being considered for treatment with ADHD drug products work with their physicians or other health care professionals to develop a treatment plan that includes a careful health history and evaluation of current status, particularly for cardiovascular and psychiatric problems (including assessment for a family history of such problems).

Finally, in response to your concern about the long-term effects of this drug class, please note that there are currently several large scale studies under way involving FDA collaborations with academic institutions, research entities, and health care providers.[2] Through these study vehicles, FDA hopes to greatly enhance our understanding and management of the benefits and risks of drugs used to treat ADHD. In the meantime,

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[1] The medicines that are the focus of the revised labeling and new Patient Medication Guides include the following 15 products:

- Adderall (mixed salts of a single entity amphetamine product) Tablets
- Adderall XR (mixed salts of a single entity amphetamine product) Extended-Release Capsules
- Concerta (methylphenidate hydrochloride) Extended-Release Tablets
- Daytrana (methylphenidate) Transdermal System
- Desoxyn (methamphetamine HCl) Tablets
- Dexedrine (dextroamphetamine sulfate) Spansule Capsules and Tablets
- Focalin (dexmethylphenidate hydrochloride) Tablets
- Focalin XR (dexmethylphenidate hydrochloride) Extended-Release Capsules
- Metadate CD (methylphenidate hydrochloride) Extended-Release Capsules
- Methylin (methylphenidate hydrochloride) Oral Solution
- Methylin (methylphenidate hydrochloride) Chewable Tablets
- Ritalin (methylphenidate hydrochloride) Tablets
- Ritalin SR (methylphenidate hydrochloride) Sustained-Release Tablets
- Ritalin LA (methylphenidate hydrochloride) Extended-Release Capsules
- Strattera (atomoxetine HCl) Capsules

[2] See http://www.fda.gov/fdac/features/2006/506_partnerships.html. The studies were also discussed at meetings of the FDA Pediatric Advisory Committee (March 22, 2006) and the Drug Safety and Risk Management Advisory Committee (February 9-10, 2006). Transcripts of these meetings are available at http://www.fda.gov/cder/drug/infopage/ADHD/default.htm.

FDA will continue to monitor the risks and benefits of these stimulants and all currently marketed drugs through annual reports, literature reviews, and reviews of spontaneous adverse event reports.

We appreciate your willingness to share your concerns with FDA.

Sincerely,

Steven K. Galson, M.D., M.P.H.
Director
Center for Drug Evaluation and Research