

August 26, 2006

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

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Citizen Petition

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to issue a regulation requiring the reformulation of stimulant drugs such as methylphenidate.

A. Action requested

The commissioner is requested to require drug manufacturers to reformulate central nervous system (CNS) stimulant drugs, such as Ritalin, Adderall, Dexedrine, Focalin, Concerta and others, as well as any generic versions, to inhibit illicit use of these drugs. The reformulation makes it difficult for the prescription version of these drugs to be converted into a powder form which can be insufflated ("snorted") or, alternatively, into a liquid form which can be injected. Under this reformulation the active moiety of the CNS stimulant is dispersed into an edible gel such as methylcellulose and then placed into a capsule. Extracting the active drug from a gel is, although not challenging to a well-trained chemist, not a trivial matter for the teenagers who typically abuse these drugs. Alternatively, the drug could be dissolved or dispersed into a water-insoluble oil, again making insufflation difficult and solution in water for injection impossible.

B. Statement of Grounds

Stimulant drugs are widely and effectively used in the United States for the treatment of Attention Deficit Hyperactivity Disorder and other medical problems. Most of the patients receiving these drugs are teenagers and young adults, the population group that is also most involved in drug abuse. There is abundant evidence that abuse of CNS stimulants either by patients or by diversion of the drugs to others is a widespread problem.

Probably the most dangerous form of abuse of stimulants is by insufflation ("snorting") or by intravenous or subcutaneous injection.

A stimulant tablet is prepared for insufflation by grinding the tablet into a fine powder; the user then sniffs the resulting powder into the nose. The tablets can be effectively ground by using a coin and an inverted aspirin bottle as a mortar

2006P-0364

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and pestle. The physical characteristics of the typical tablet are such that converting it into a fine powder with this simple equipment is fast and effective.

CNS stimulants can be prepared for injection by dissolving the tablet in water, drawing up the solution into a syringe and then injecting it. Commonly available insulin syringes are frequently diverted for this use.

Because these methods of abusing stimulants deliver the drug rapidly and in high concentration to the CNS, their effects are compared to the effects of cocaine.

Documentation of the extent of the problem and the methods for preparing stimulant drugs for insufflation or injection is abundantly available at the web sites of the National Drug Information Center and the Drug Enforcement Administration:

<http://www.usdoj.gov/ndic>

and

<http://www.usdoj.gov/dea>

This dangerous abuse of stimulant drugs can be significantly reduced by reformulating the form in which they are dispensed. If the drug cannot be converted into a powder or be dissolved in water, neither snorting nor injection will be possible. One way to do this is to disperse the drug in an inert non-water-based gel-like substance such as methylcellulose, or an inert non-water-soluble oil, which in turn would be enclosed in a capsule. Taken orally, the drug would retain the bioavailability of the standard tablet, but it would no longer be possible to insufflate or inject it.

Other reformulations might be considered. For example, it might be possible to find a chemical that could be mixed with the stimulant drug that would cause it to be painful to insufflate. Capsaicin might fill this role. The drawback to this is that, unlike methylcellulose, capsaicin and other chemicals may well make the tablet unpalatable, and might, in susceptible individuals, cause allergic reactions.

Stimulant drugs are available as transdermal skin patches. These clearly inhibit the insufflation and injection routes of abuse, but are not without drawbacks. Skin patches reveal their use to others, and may make the user subject to discrimination. Absorption through skin patches is slower and less reliable. Thus transdermal patches, although valuable, cannot replace oral formulations.

C. Environmental Impact

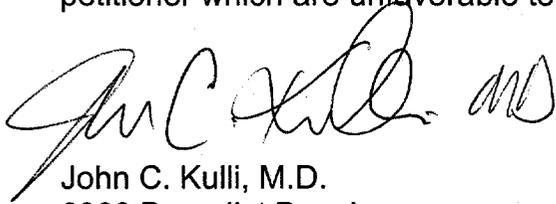
The proposed change in formulation does not increase the use of the active moiety and therefore is categorically excluded, and does not require the preparation of an environmental impact statement (21CFR Sec. 25.31(a)).

D. Economic Impact

To be submitted if requested.

E. Certification

The undersigned certifies, 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 petitioner which are unfavorable to the petition.

A handwritten signature in black ink, appearing to read "John C. Kulli, M.D.", with a stylized flourish at the end.

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