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Dockets Management
United States Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville MD 20852
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RE: Risperdal® M-Tab Promulgation

2006P-0147

I oppose the proposed regulation.

This petition requests a determination of whether Risperdal® M-Tab was voluntarily withdrawn from sale. NDA 21-444 is still a marketed product, and attached NDA 21-444 from FDA's website. I also included labeling in several attachments for the determining party to consider.

NDA 21-444 was not withdrawn from sale, **and it should never have been for sale.** I call FDA's attention to an attachment dated January 1999. FDA was concerned about a Risperdal® geriatric campaign prior to FDA approval. Risperdal® was misbranded on that date in 1999 as a marketed product.

FDA reviewed the marketing of Risperdal® (risperidone) *before there should have been any marketing.* Risperdal® **still is not approved** for consumption per 'FDA standards' and a citizen petition has been filed.

Materials previously found in violation of the Federal Food, Drug, and Cosmetic Act in one attachment included (but not limited to):

Sales aids journal ads, a display panel, brochures, a letter, more journal ads, more letters, a flashcard, a calendar, and a computer program.
Cited as false and misleading was the "geriatric campaign" (see labeling) which FDA found the safety of Risperdal® had not been established in "fragile" individuals with concomitant illnesses, and safety and efficacy in treating "hostility" in the elderly¹.

¹ SEE FDA PUBLIC HEALTH ADVISORY REGARDING ELDERLY PATENTS

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FDA found "efficacy issues" false and misleading for a broad range of diseases and disorders including **schizophrenia, schizophreniform disorder, schizoaffective disorder, bipolar disorder, and elderly psychosis.**

FDA's Regulatory Reviewer Lisa Stockbridge sent a stern letter by facsimile to the Janssen Research Foundation. Ms. Stockbridge cited Risperdal®² comparative claims, quality of life claims, safety, efficacy, and MACMIS ID 6908 clearly indicates marketing for unapproved uses. Prior to safe for use as prescribed, and miserably failed efficacy.

Why has no one misbranded Risperdal, by removing this psychotropic drug from the market?

Also of note is the active ingredient of Risperdal® (risperidone). This has multiple NDA's and 4 drug products with the *same active ingredient* (including any salt or ester). FFDCA **expressly forbids** approving the same active ingredient in this many new drug applications at once.

Risperdal® has been misbranded in the previous millennium, and now in 2006 FDA approved labeling attached has two tablets taken orally, an oral solution, and an injection called Risperdal Constra.

FDA's Lisa Stockbridge notes in the letter two NDA's for two Risperdal® products: NDA 20-722 and 20-588. FDA now has labeling for four Risperdal products with NDA's contrary to her letter.

FDA should remove all previously misbranded drugs, **and search FDA DDMAC's website for such and withdraw applications.** FDA is being informed of drugs it failed to remove after they were misbranded, and for up to 7 years.

DDMAC is not shy about misbranding, but there is a failure to remove the drug for some reason. Look what happens when law is not enforced. Look at your Medwatch data for Risperdal® that never should have been ingested. **FDA's inaction cause adverse events.** Letters are irrelevant in absence of regulatory action.

I have no legal obligation to report such, the United States Department of Health and Human Services has the obligation. HHS, specifically FDA, is

² THIS APPEARS TO BE USED AS RITALIN® FOR THE ELDERLY OFF LABEL.

failing miserably. The Federal Register is being substituted for your legal obligation to protect the public. Without affirmative action, it is apparent the public pays the price.

The FDA should withdraw all applications, and immediately recall the misbranded drugs FDA missed way back in 1999.

Anything short of above is another failure to protect the public health.

Numerous attachments in support of failure are included.