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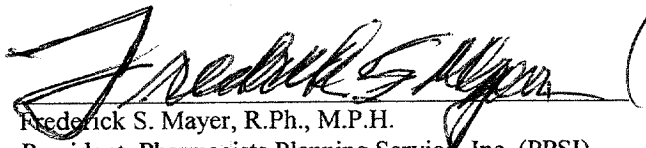
Documents Management Branch
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane, Room 4-62
Rockville, MD 20852

September 23, 2006

The undersigned submits this Petition under Section 21 CFR 10.20 and 21 CFR 10.30 and other pertinent sections of the Federal Food, Drug and Cosmetic Act or any other statutory provision which authority has been delegated of the Commissioner of Food and Drug to request the FDA Commissioner to regulate labeling and packaging of Acetaminophen/APAP containing products.

We strongly request that you consider this petition, immediately!!

Signature
Name of Petitioners:



(See Original Inside)

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2006P-0423

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Dockets Management Branch,
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October 11, 2006

The undersigned submit this Petition under Section 21 CFR 10.20 and 21 CFR 10.30 and other pertinent sections of the Federal Food, Drug and Cosmetic Act or any other statutory provision which authority has been delegated of the Commissioner of Food and Drug to request the FDA Commissioner to regulate labeling and packaging of Acetaminophen/APAP containing products.

ACTIONS REQUESTED:

1. Mandate all non-aspirin containing OTC medicines with Acetaminophen/APAP to be clearly labeled "Contains Acetaminophen. Do not take with any other Acetaminophen/APAP"
2. Regulate maximal Acetaminophen/APAP dosage/number of pills. We suggest 500 mg. tablets to be no more than 32 or 16 in a pack, that is 16 or 8 gms. and that the pack be mandated to be in blister packs
3. Mandate the association of Acetaminophen/APAP containing tablets with an FDA-approved MedGuide detailing the recommended dosages and possible adverse drug events of these products, including increased risks with chronic alcohol consumption.

Multiple FDA-issued letters and Board of Pharmacy letters, January-February, 2003, FDA Consumer Magazine articles both Dr. Stephen Galson, M.D., MPH of the FDA, have addressed the above issues without substantive regulatory action or a decrease in APAP toxicity cases; in fact, liver toxicity from APAP is now the number one cause of acute liver failure in the United States (see below).

STATEMENTS OF SCIENTIFIC BASIS FOR PETITION:

1. Acetaminophen/Tylenol products are marketed for pain relief, to reduce fevers, headaches, toothaches, sore throats, migraines, neuralgia, menstruation pain, backaches, aches and pains from cold and flu and many other medically indicated conditions.

2. Most consumer/patients do not know that Tylenol is Acetaminophen (APAP).

3. Most consumer/patients do not know that Acetaminophen (APAP) is present in > 100 preparations with different names. 38% patients with APAP-induced liver failure took two different preparations containing APAP (1)

4. Most consumer/patients are not aware that there are a number of scientific reports stating that chronic alcohol use is associated with more severe outcome. It is usually stated that if a patients consumes three or more alcohol beverages daily, he/she should take no more than 2 gm. of APAP daily vs. the official maximum recommended dose of 4 g. Acute liver failure has been well documented in these cases (1, 2)

5. The minimum APAP intake associated with unintentional toxicity was 1 gram/day, well below the maximum recommended dose (1)

6. The number one generic prescription drug being dispensed in the USA today is Vicodin and its generic equivalent Hydrocodone Bitartrate with Acetaminophen, 5 mg-500 mg with over 100 million prescriptions. Vicodin as well as other similar narcotic-containing combinations contain Acetaminophen (APAP) anywhere from 325 mg to 750 mg. A recent study suggested that 62% of unintentional APAP overdoses leading to acute liver failure were using a narcotic-containing preparation, often for more than 30 days suggesting addiction to the narcotic with gradual increasing dosage (4).

7. Acute liver failure (ALF) cases caused by Acetaminophen/Tylenol rose from 28% in 1998 to 51% in 2004 and was 49% in 2005. This research project was conducted by the US Acute Liver Failure Study Group (ALFSG). Acetaminophen hepatotoxicity far exceeds other causes of acute liver failure in the United States (1, 5).

8. The ALFSG also found that 178 or 65% of 275 patients identified as having APAP-induced liver toxicity survive. 74 patients, or 27%, died without a liver transplant; 23 patients, or 8%, underwent a liver transplant operation (5).

9. Recently the administration of therapeutic dosages of APAP to normal volunteers resulted in their tripling their baseline transaminases in 65% of the cases. About 40% of normal individuals developed transaminases > three times the upper limit of normal (6).

References:

1. Blendis L. Gastroenterology 2006;131:963-4.
2. Draganov P et al. Postgrad Med 2000;107(1):189-95
3. Drug Topics Magazine online, March 20, 2006.
4. Drug Topics Magazine, August 7, 2006, pp. 63-65
5. Larson et al. Hepatology 2005;42:1364-1372.
6. Watkins P et al. JAMA 2006;296:87-93.

There is no environmental impact associated with this Citizen's Petition and we wish to be excluded under 21 CFR Sec. 25.24.

The undersigned certify, that, to the best knowledge and belief of the undersigned this Petition includes all information and view on which the Petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the Petition (21 CFR Sec. 10.30b).

Signature

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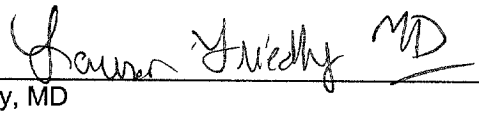

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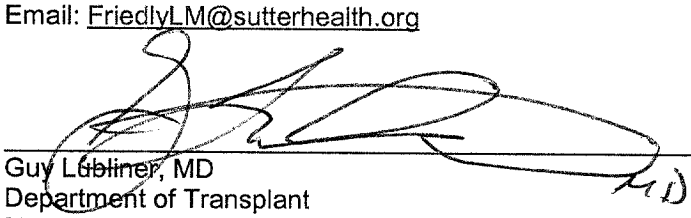

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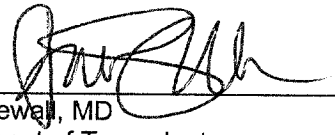

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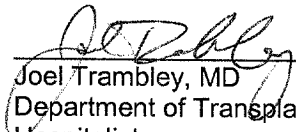

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