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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD, 20852

Comments On Petition 2006P-0090

I agree with immediately removing from the market propoxyphene HCL (Darvon) and all propoxyphene-containing products.

The "D"'s at drugs @ FDA:

DARVOCET (ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE)

DARVOCET A500 (ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE)

DARVOCET-N 100 (ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE)

DARVOCET-N 50 (ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE)

DARVON (PROPOXYPHENE HYDROCHLORIDE)

DARVON COMPOUND (ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE)

DARVON COMPOUND-65 (ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE)

DARVON W/ ASA (ASPIRIN; PROPOXYPHENE HYDROCHLORIDE)

DARVON-N (PROPOXYPHENE NAPSYLATE)

Darvon was approved on 08/16/1957. It has one strength DISCN in the Orange Book. Darvon never performed clinical investigations demonstrating safety and efficacy. This petition raises both issues of safety and efficacy.

Darvocet is an unapproved drug. It has one action date of 10/18/1972 which was NDA approval.

I agree in principle with Sidney Wolfe from Public Citizen. The removal of drugs that are highly diverted and abused with 23 million prescription is well presented, with well referenced data. The DEA stating the ease of obtaining a prescription is the main reason for such.

The United States is a party to the Single Convention on Narcotic Drugs, 1961,

and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.

If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section. - 21 USC Sec. 811(d)(1)

I support the petition in part, and misbranding the unapproved drugs. Recall all propoxyphene based products for safety and efficacy reasons, including those that reference Darvon and Darvocet.

David Lowe

Ida, Michigan