Buchanan Ingersoll
ATTORNEYS

Donald E. Segal
202-452-7959
segalde@bipc.com

PRINCIPAL LOCATIONS
PHILADELPHIA
PITTSBURGH
PRINCETON
LONDON
MIAMI
BUFFALO
NEW YORK CITY
HARRISBURG
TAMPA
WASHINGTON, DC

May 18, 2001

VIA COURIER

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 123
Rockville, MD 20857

RE: Sidmak Laboratories, Inc.'s Citizen's Petition

Dear Sir or Madam:

Enclosed please find an original and three duplicates of Sidmak Laboratories, Inc.'s Citizen's Petition to request a determination that Wyeth Ayerst's application for Disulfiram (New Drug Application #07-883) was withdrawn from the market for reasons other than safety or effectiveness. This submission is made pursuant to the Federal Food Drug and Cosmetic Act and 21 C.F.R. §§ 10.25(a), 10.30, and 314.161.

Any correspondence regarding this petition should be directed to Roger Schwede at Sidmak Laboratories, Inc. 17 West Street, P. O. Box 371, East Hanover, NJ 07936. Phone (973) 599-4352.

Sincerely,

Donald E. Segal

Donald E. Segal
202-452-7959

ENCLOSURE

DIP-0245

CP1

Sidmak LABORATORIES, INC.

17 WEST STREET ● P.O. BOX 371 ● EAST HANOVER, NJ 07936 ● TELEPHONE: (973) 386-5566 ● (800) 922-0547

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May 4, 2001

VIA HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Citizen's Petition to request a determination that Wyeth Ayerst's application for Disulfiram (New Drug Application #07-883) was withdrawn from the market for reasons other than safety or effectiveness.

Sidmak Laboratories, Inc. ("Sidmak") respectfully submits this petition, pursuant to the Federal Food Drug and Cosmetic Act ("FFDCA"), and 21 C.F.R. §§ 10.25(a) and 10.30 to request the Commissioner to make a determination pursuant 21 C.F.R. § 314.161 that Wyeth Ayerst's application for Disulfiram (New Drug Application ("NDA") #07-883) was voluntarily withdrawn from the market for reasons other than safety or effectiveness.

I. ACTION REQUESTED

Sidmak requests that the Commissioner, through the appropriate officials within the Food and Drug Administration's ("FDA") Center for Drug Evaluation and Research ("CDER") make a determination pursuant 21 C.F.R. § 314.161 that Wyeth Ayerst's application for (NDA #07-883) was voluntarily withdrawn from the market for reasons other than safety or effectiveness.

II. STATEMENT OF GROUNDS

Sidmak is the parent company of the wholly owned subsidiary Odyssey Pharmaceuticals ("Odyssey"). In December 2000, for full and fair consideration, Sidmak acquired all rights to

NDA #07-883 for Disulfiram (tradename "Antabuse") from the previous owner, Wyeth Ayerst, including the NDA, all the underlying safety and effectiveness data, and the tradename. Concurrent with the negotiations for this sale, Wyeth Ayerst discontinued the marketing of its Disulfiram product. Odyssey does not wish to continue to market under the NDA as they are the holder of separate approved applications for Disulfiram under Abbreviated New Drug Applications ("ANDAs") #88-482 (250mg) and #88-483 (500mg).

Odyssey notified FDA's Office of Generic Drugs ("OGD") of its intent to market the Disulfiram products (ANDAs #88-482 and 88-483) under the newly acquired tradename "Antabuse." OGD stated that given the particular facts surrounding the situation, Odyssey could use the tradename "Antabuse" for its Disulfiram products (ANDAs #88-482 and 88-483); however, OGD stated that a petition would be required to determine that NDA #07-883 had been withdrawn from sale for reasons other than safety or effectiveness. This petition is made in response to that request.

Ordinarily a petition to request a determination of whether a drug was withdrawn for reasons other than safety or effectiveness is made prior to the filing of an ANDA for the withdrawn drug. Odyssey owns all rights and data associated with Wyeth Ayerst's NDA and will continue to maintain the NDA. The approval of the NDA was never withdrawn or surrendered. Marketing of the drug product was discontinued solely for commercial reasons. This petition therefore is being filed in response to FDA's specific request.

As current owner of the NDA, Sidmak has full access to all data and information within the NDA, and is not aware of any evidence that would suggest that it's decision to discontinue

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sale of the product from the market place under the application raises any questions of potential safety of efficacy problems.

For the forgoing reasons, the petitioner respectfully requests that the Commissioner take the requested action.

III. ENVIRONMENTAL IMPACT

In accordance with 21 C.F.R. § 25.31(c), an environmental impact analysis is not required.

IV. CERTIFICATION

The undersigned certifies that, the best of the undersigned's knowledge and belief, this petition includes all information and views on which the petition relies. Further, this petition includes representative data, favorable and unfavorable, that are presently available to the petitioner.

Mr. Roger Schwede
VP, Regulatory Affairs and R&D
Sidmak Laboratories, Inc.
17 West Street
P.O. Box 371
East Hanover, NJ 07936