

ROUTING SLIP
GENERATED BY: HF-40
DATE: APR 09, 2004

FDA CONTROL NUMBER: 04 2227

TRACER #: **OS #:**

DATE OF CORRESPONDENCE: 04/01/04

DATE INTO FDA: 04/06/04

TO: LESTER M CRAWFORD, ACTING COMMISSIONER OF THE FOOD AND DRUG
ADMINISTRATION

FROM: DONNA J HARRISON, M.D., AMERICAN ASSOCIATION OF PROFILE OBSTETRICIANS
AND GYNECOLOGISTS

SYNOPSIS: WRITES RE: CITIZEN PETITION 02P-0377 FILED WITH FDA IN AUGUST
2002 REQUESTING REPEAL OF THE APPROVAL OF MIFEPRISTONE. REQUESTS
FDA RESPONSE.

LEAD OFFICE: HFD-1

HOME OFFICE: HF-40

CONTACT/PHONE#: CAPRI R MCCLENDON 301-827-5903

COPIES: GENERAL DISTRIBUTION

HF-1 LESTER M CRAWFORD

HF-3 MURRAY M LUMPKIN

HF-10 PETER PITTS

HF-1 MARY L REUTHER

HF-2 JANET WOODCOCK

HF-1 AMIT SACHDEV

HF-40 LA JUANA D CALDWELL

HF-40 WALTER D OSBORNE

HF-40 ELIZABETH A CLARKE

HFA-305

COORDINATION:

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
----- HFD-1	----- PREPARE DIRECT REPLY	----- 04/21/04
REMARKS: PLEASE FORWARD COPY OF RESPONSE TO CAPRI MCCLENDON AT HF-40. THANK YOU.		

AAPLOG - AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS

EXECUTIVE OFFICE: AAPLOG 339 River Ave, Holland, MI 49423 Website: www.aaplog.org

Telephone: (616) 546-2639 Fax: (616) 396-3160 E-Mail: prolifeob@aol.com

April 1, 2004

04-06-04P03:49 RCVD

Dr. Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Room 1471
Rockville, MD 20857

Re: Docket No. 02P-0377

Dear Dr. Crawford:

The American Association of Pro-life Obstetricians and Gynecologists, the largest special interest group within the American College of Obstetricians and Gynecologists, in August 2002 filed a Citizen Petition with the FDA, requesting repeal of the approval of mifepristone (Mifeprex). We were joined in this petition by Concerned Women for America and the Christian Medical Association. Danco, the American distributor of mifepristone, responded to our petition in March 2003, and we replied in October 2003.

FDA has not yet responded to the concerns we voiced in our submissions to the FDA. These concerns are serious and affect the health of large numbers of American women. Two American women are now dead from Mifeprex, and, we understand, FDA has received at least 470 severe adverse event reports related to the use of this drug.¹ We respectfully ask that you devote agency attention immediately to answering the concerns raised in our Citizen Petition. We look forward to an agency response to the Petition within the next two months.

Respectfully submitted,



Donna J. Harrison, M.D.
Chairman, Subcommittee on Mifeprex
American Association of Pro-life Obstetricians and Gynecologists
P.O. Box 414
Eau Claire, MI 49111
269-461-3412

President

Byron Calhoun, MD
Rockford, Illinois

Vice President

Joseph L. DeCook, MD
Holland, MI

Secretary

Elizabeth Shadigian, MD
Ann Arbor, MI

Treasurer

Donna Harrison, MD
Eau Claire, MI

Immediate Past President

Pamela E. Smith, MD
Chicago, IL

¹ Also of concern is the recently publicized death of a Swedish teenager resulting from her mifepristone abortion.

Copies Sent to:

The Honorable Claude A. Allen
Deputy Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Ave., Room 606G
Washington, D.C. 20201

Mr. Daniel Troy, Esq.
Associate General Counsel
Food and Drug Administration
5600 Fishers Lane, Room 605
Rockville, MD 20857

Mr. Peter H. Wehner
Office of Strategic Initiatives
The White House
Washington, DC 20500

The Honorable John McCain
U.S. Senate
241 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Joe Barton
U.S. House of Representatives
2109 Rayburn Building
Washington, D.C. 20515

The Honorable Jim DeMint
U.S. House of Representatives
432 Cannon House Office Building
Washington, D.C. 20515

The Honorable Mark Souder
U.S. House of Representatives
1227 Longworth House Office Building
Washington, D.C. 20515