Judicial Watch

Because no one is above the law.

October 13, 2000

VIA CERTIFIED MAIL AND FAX (301 443-1726)

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Re: Freedom of Information Act Request

Dear Sir/Madam:

Pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. 552, and its regulations, we hereby request from the Food and Drug Administration (FDA), all correspondence, memoranda, documents, reports, records, statements, audits, lists of names, applications, diskettes, letters, expense logs and receipts, calendar or diary logs, facsimile logs, telephone records, call sheets, tape recordings, video recordings, notes, examinations, opinions, folders, files, books, manuals, pamphlets, forms, drawings, charts, photographs, electronic mail, and other documents and things, that refer or relate to the following in any way:

1. The production of RU-486 (Mifeprex or mifepristone) by Hua Lian Pharmaceutical, and its parent corporation, Shanghai Pharmaceutical Group.

2. All reports by FDA inspectors of Hua Lian Pharmaceutical factory, to include the July 2000 inspection.

501 School Street, SW Suite 725 Washington, DC 20024 Tel: (202) 646-5172 Fax: (202) 646-5199

3. FDA requirements that the Hua Lian must satisfy and/or attain in order to produce RU-486 in pill form.

4. Hua Lians Pharmaceutical's failure to meet certification requirements to produce RU-486 in pill form.

5. Any and all documents regarding Danco Laboratories, Neogen Pharmaceuticals, Neogen Industries, Advances/Neogen Group, and/or Exelgyn in relation to RU-486; including, but not limited to the manufacturing, production, and distribution of RU-486.

6. The application and documentation submitted by the Population Council in relation to the FDA's approval of RU-486.

7. All documents regarding the Population Council in relation to RU-486, including the patent transfer of RU-486 to the Population Council.

8. All documentation regarding the Rockefeller Foundation, Concept Foundation, World Health Organization, and the World Bank in relation to RU-486.

9. The FDA decision not to disclose the name or location of the manufacturer of RU-486.

Thank you for your expected cooperation in responding timely to our request, which should be within 20 working days as required under the Act, because time is of the essence.

Pursuant to the FOIA, if any portions of the requested documents are claimed to be privileged, those portions which are not claimed to be privileged should be provided to the undersigned. This should be done prior to the conclusion of the statutory 20-day period for

response. In addition, under the FOIA there is an absolute requirement to produce those segregable portions of documents which are not claimed to be privileged, as well as a list ("Vaughn Index") that indicates by date, author, general subject matter, and claims of privilege(s) those documents, or portions thereof, which have been withheld or not provided. Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir 1973), cert. denied, 415 U.S. 977 (1974); Iglesias v. Central Intelligence Agency, 525 F. Supp. 547 (D.C. 1981); see generally LaRocca v. State Farm Mut. Auto. Ins. Co., 47 F.R.D. 278 (W.D. Pa. 1985).

We note that President Clinton instructed agencies in October, 1993, to ensure compliance with both the spirit as well as the letter of the Act. *See* President Clinton's FOIA Memorandum, U.S. Department of Justice, FOIA Update, Summer/Fall 1993, at 3. In addition, Attorney General Reno issued a FOIA Memorandum in October, 1993, which *inter alia* states "I strongly encourage your FOIA officers to make 'discretionary disclosures' whenever possible under the Act," and orders "a presumption of disclosure." *See* Attorney General Reno's FOIA Memorandum , U.S. Department of Justice, FOIA Update, Spring 1994, at 1-2.

Judicial Watch is entitled to a public interest fee waiver for this request. At 5 U.S.C. § 552 (a)(4)(A)(iii), the FOIA sets forth a two prong test to determine whether a fee waiver is appropriate. First, the disclosure must be in the public interest by contributing significantly to the public's understanding of the operations of the government. *Schrecker v. Department of Justice,* 970 F. Supp. 49, 50 (D.D.C. 1997); *Fitzgibbon v. Agency for International Development,* 724 F. Supp. 1048, 1050 (D.D.C. 1989); *Larson v. Central Intelligence Agency,* 843 F.2d 1481, 1483 (D.C. Cir. 1988). Second, the disclosure must not be primarily in the commercial interest of the requester. *Schrecker,* 970 F. Supp. at 50; *Fitzgibbon,* 724 F.2d at 1050; *Larson,* 843 F.2d at 483.

Judicial Watch is a 501 (c)(3) not-for-profit public interest organization. One of its purposes is to provide the public with information which exposes government activities that are contrary to the law. Judicial Watch is, in effect, an educational foundation, as well as a law firm,

which uses several mechanisms for the dissemination of the information it acquires, and operates to ensure that this information will be made available to the public on a daily basis:

- Judicial Watch, as a press entity itself, produces several press releases each week.

- The *Judicial Watch Newsletter* has a monthly circulation of over 300,000 copies nationwide.

- Judicial Watch maintains a website on which people can view copies of, among other things, FOIA documents, press releases, responsive documents, deposition transcripts and court opinions. This website is viewed by over 20,000 people per day on average, and on a few occasions, had logged up to 1,000,000 visitors in a single day.

- Over 60,000 people subscribe to our "Infonet" listserve for daily updates on our lawsuits, FOIA requests, investigations and public education programs.

- Judicial Watch's Chairman has been invited to testify before Congressional committees as an expert witness on legal matters, including, but not limited to the Privacy Act and the Freedom of Information Act.

- Judicial Watch's Chairman and other employees frequently appear on nationally broadcast radio and television programs to provide information, analysis and commentary concerning government corruption and other legal issues.

- Judicial Watch has been credited by Courts, the Congress and various other media outlets on several occasions for uncovering information and documents concerning government corruption, illegal and/or inappropriate activities, and documented instances of government attempts to "stonewall" requests for information and

accountability in the public interest.[1]

- Judicial Watch is involved in the production and broadcast of a monthly one hour news and information television program, *Public Disclosure,* fashioned after the long running news broadcast *60 Minutes*. *Public Disclosure* is syndicated across the country.

- Judicial Watch produces its own weekly radio program, *The Judicial Watch Report*, which airs nationwide on 36 stations and on the Internet. Judicial Watch disseminates information it obtains through this medium as well.

- Judicial Watch hosts and sponsors conferences and rallies as public education forums for the dissemination of the information it acquires. For example, Judicial Watch will host an ***Ethics in Government 2000 Conference*** at the Washington Hilton on October 20-21 2000.

In short, Judicial Watch's efforts to expose government corruption make news on almost a daily basis, and it functions, in part, as a member of the media.

Clearly, information that exposes government activity that is contrary to the rule of law will contribute significantly to the public's understanding of the operations and activities of government. In fact, according to the *Office of Management and Budget, Freedom of Information Reform Act of 1986 – Uniform Freedom of Information Act Fee Schedule Guidelines,* § 67(g), this is one of the categories of activity which courts have characterized as in the public interest.

This FOIA request is based upon reporting in several news outlets, to include *The*

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[1]See attached press releases.

Washington Post[2], that appears to allege inappropriate or unlawful activities by the FDA and/or its officers, employees, and/or agents. In this case, the public's understanding of the actions and activities of the FDA with regard to RU-486 is an issue that merits full and immediate disclosure.

Congress has spoken clearly on this subject by amending FOIA so that it can "be liberally construed in favor of waivers for noncommercial requesters." *McClellan Ecological Seepage Situation,* at 1284 (quoting 132 Cong. Rec. S14298 (Sept.30, 1986). The main purpose of the amendment, according to Senator Leahy, was to prevent gamesmanship on the part of government agencies i.e., to "remove roadblocks and technicalities which have been used by various Federal agencies to deny waivers or reductions of fees under FOIA." *Id.* (quoting 132 Cong. Rec. S16496, October 15, 1986).

We request expeditious handling and immediate release of the requested information in the public interest. The health and safety of the US public may be at grave risk due to the questionable purity and safety of Chinese pharmaceutical products, standards, practices. The extraordinary steps taken by the FDA – the unprecedented refusal to disclose identifying information concerning the manufacturer of pharmaceuticals intended for the US citizens, that FDA officials have sworn to protect – is an outrageous act that calls into question exactly what public service the FDA is providing. These highly irregular, secretive actions on the part of the FDA, in relation to the approval of the controversial RU-486 pill, demand the immediate and full disclosure of the information requested in this letter for the sake of the health and safety of the US public. No other interest, issue or agenda can "trump" the American public's right to accountability from its "trusted servants" in the FDA – who are charged with protecting the public's health and safety. Denying the American public information about pharmaceuticals that the FDA has approved for their use does not help or protect them in any way.

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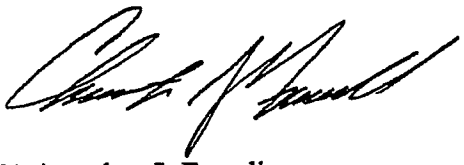
[2] "Chinese to Make RU-486 For U.S.," By Philip P. Pan, *Washington Post Foreign Service*, Thursday, October 12, 2000; PageA01, found at: http://www.washingtonpost.com/wp-dyn/articles/A53938-2000Oct11.html (attached).

Release of the information will promote confidence in an honest democratic system, and contribute to furthering the integrity of the American national government by deterring and/or sanctioning corrupt activities. The failure to do so will likely result in the further compromise of important interests of the American people.

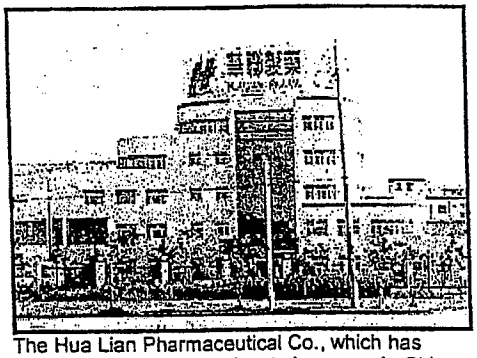
Sincerely,
JUDICIAL WATCH, INC.



Christopher J. Farrell

Chinese To Make RU-486 For U.S.

By Philip P. Pan
Washington Post Foreign Service
Thursday, October 12, 2000; Page A01



The Hua Lian Pharmaceutical Co., which has produced RU-486 for at least nine years in China, is preparing to export the controversial abortion drug to the United States. (Philip P. Pan - The Washington Post)

SHANGHAI, Oct. 11 — The Hua Lian Pharmaceutical factory emerges from fields of sorghum and green onions an hour's drive south of downtown Shanghai. At quitting time, workers board company buses that take them back to the city. Others leave on bicycles, pedaling toward nearby villages along narrow lanes dotted with oxen.

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Despite the tranquil appearance, the Hua Lian plant is a secret factory of sorts. Its name and location are shielded not by Chinese authorities, but by the U.S. Food and Drug Administration, which two weeks ago approved the sale of a product that workers here are preparing to churn out for the American market--the abortion drug RU-486.

Supporters of RU-486, which offers an alternative to surgical abortions, have for years sought a manufacturer to produce it for the U.S. market, ever since boycott threats by antiabortion activists led the drug's French developers to renounce U.S. production in 1992. For eight years, no pharmaceutical company would develop it for sale in the United States.

So when the FDA announced it had approved the sale of RU-486, it took the unprecedented step of refusing to disclose the name or location of the manufacturer, citing concerns about employee safety and security. The drug's U.S. distributor, Danco Laboratories, also refused to identify the firm.

But several Chinese officials and the head of a Bangkok-based foundation that has worked closely with the company confirmed today that Hua Lian Pharmaceutical Co. will produce the drug for the United States.

An FDA official in Washington declined to comment, citing the agency's position that it would not disclose the location of the manufacturing site.

Danco said in a statement from its New York offices that the site was inspected by the FDA to make sure it met the agency's requirements but that it could not identify the plant or comment on its location because of a confidentiality agreement.

The fact that a state-owned company in China will be producing RU-486, or mifepristone, for U.S. consumers could become part of a debate over the drug in the United States. Told of the Chinese factory's role, U.S. antiabortion activists said they intend to question the safety and purity of Chinese pharmaceuticals and tie the drug to China's controversial one-child policy and human rights record.

Douglas Johnson, legislative director of the National Right to Life Committee, said his group found the news "very disturbing." He also criticized the FDA for its refusal to reveal that the manufacturer was in China, saying the agency's rationale was "highly implausible."

"They said they wanted to protect the company from violence or protests, but it's ludicrous to say that is an issue in China, where demonstrations aren't permitted," he added. "It's a public relations problem they want to avoid--they don't want the association with Chinese coercive abortion practices."

RU-486 has been a key ingredient in China's population control strategy for years. Of the estimated 10 million abortions performed annually in China, about half are carried out with RU-486, said Gao Ersheng, director of the Shanghai Institute of Planned Parenthood Research.

Hua Lian has been making RU-486 for at least nine years, one of three companies in China that manufacture the drug. Established in 1939 and nationalized after the 1949 Communist revolution, it is one of the largest pharmaceutical firms in China, according to its Web site.

With the help of the Rockefeller Foundation and the Bangkok-based Concept Foundation, the company has been working for three years to upgrade its equipment and retrain its staff to meet international standards in order to be permitted to export the drug.

The Concept Foundation was established by the World Health Organization and World Bank in 1989 to assist factories in developing countries to make medical products at low cost for Third World health agencies. The Rockefeller Foundation gave $2 million to the group in 1997 to help Hua Lian and China's state family planning agency upgrade the factory.

Joachim Oehler, who heads the Concept Foundation, said the goal was to enable Hua Lian to produce export-quality RU-486 to be used in China and elsewhere as an emergency contraceptive. He said the foundations knew that would also allow Hua Lian to export the drug to be used for inducing abortions, but that that was not their goal.

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Oehler said FDA inspectors spent a week at the factory in July and agreed to allow Hua Lian to produce RU-486 in bulk amounts for export to the United States. The factory is not certified to export RU-486 in pill form, but Oehler said he expects it to meet those standards in three to five months.

In the meantime, he said, Hua Lian will send RU-486 in amounts of about 100 pounds to another factory that will make it into pills. He said he does not know the location of the other factory but assumes it is in the United States and does not know if other factories elsewhere might manufacture the drug for U.S. use.

"If you compare it with other manufacturers in China, they are among the tops in terms of their production standards," Oehler said of Hua Lian. "The factory is in very good shape. It would not have survived the FDA inspection otherwise."

The Hua Lian Pharmaceutical Co. denied multiple requests for interviews or a tour of the factory, as did its corporate parent, the Shanghai Pharmaceutical Group Corp. But Gao and three Hua Lian officials said the factory will be making RU-486 for export to the United States.

Oehler said it is unclear how much RU-486 the factory will produce annually, but he said it can manufacture at least half a ton a year, or enough to meet the entire world demand.

Neither abortion nor RU-486 is a subject of moral debate in China in the way it is in the United States.

During the first decades of Communist rule, government authorization was required to obtain an abortion, and it was often difficult to obtain, especially for unmarried women. As a result, women often sought abortions from illegal providers, who often prescribed various forms of folk medicine. In the 1970s, though, China began to adopt population control measures and the government changed its policy, allowing women to obtain abortions without government approval.

China began experimenting with RU-486 as early as 1983, participating in clinical trials with the World Health Organization. In 1988, along with France, it became one of the first countries to approve the drug. By the mid-1990s, the drug had become popular for women seeking an alternative to surgical abortion.

Gao, the director of the research institute, attributed the popularity of the drug in part to the fact that most surgical abortions in China are performed without anesthesia and are thus extremely painful. In addition, many Chinese women choose RU-486 because they fear that complications during surgical abortions might harm their ability to have

children later, other experts said.

"RU-486 has given women more choices, and it's been beneficial to women's health. It has also helped us limit the growth of the population," Gao said.

He also said he was not surprised by the debate in the United States. "My feeling is that isn't should be opposed. But if you oppose abortion, I understand. But you shouldn't oppose it just because it's made in China. That shouldn't matter at all."

Staff writer Marc Kaufman in Washington contributed to this report.