SAMPLE LETTER TO FDA OFFICIALS ON IL-2

May 19, 1991

Dr. Gerald Quinan, Dr. Jay Siegel, Dr. David Kessler
Food and Drug Administration
5600 Fishers Lane
Bethesda, Maryland 20857

Dear Dr. _____:

I urge the FDA to approve IL-2 immediately. As a cancer patient suffering from metastatic kidney cancer; the failure of the FDA to approve this drug is a disservice to the public.

IL-2 was developed with tax dollars at the NCI. It has been approved in Europe, and it has demonstrated its effectiveness in treating kidney cancer. We are entitled to benefit from the research we have paid for.

Last summer, the FDA reviewed IL-2. Rather than it approve this drug, it asked for more research information. I assume that FDA has received the information it requested. Therefore, why has no decision been made? Is there going to be another hearing? If so, when?

Patients such as myself are aware of the side effects of IL-2, and readily accept the risks of IL-2. What we can't accept is an FDA that is slow in getting us the drugs we need.

You are a public employee. You are supposed to work for me and other tax payers. I suggest that you start meeting the needs of kidney cancer patients. You should approve IL-2 without delay, or offer us a better treatment. If you have no better treatment to offer us, you have a moral obligation to approve IL-2 immediately and to help us.

Given all the time that the FDA has already spent on IL-2, if you can't make a decision within 30 days, we will need to get some new administrators who are motivated to act faster. You can be sure that I will write to my congressmen and to the White House in order to bring about employee changes at the FDA.

Do not take time to write me back. Your approval of IL-2 within the next 30 days is the only response that I will accept.

Sincerely,

FDA BACKGROUNDER
CURRENT & USEFUL INFORMATION FROM THE FOOD & DRUG ADMINISTRATION

Making Your Voice Heard at FDA

How to Comment on Proposed Regulations and Submit Petitions

As a regulatory agency, FDA publishes rules that establish or modify the way it regulates foods, drugs, biologics, cosmetics, radiation-emitting electronic products, and medical devices—commodities close to the daily lives of all Americans. FDA rules have considerable impact on the nation's health, industries and economy. These rules are not created arbitrarily or in a vacuum. They are formed with the public's help.

By law, anyone can participate in the rule-making process by commenting in writing on rules FDA proposes. FDA allows plenty of time for public input and carefully considers these comments when it draws up a final rule.

FDA gathers public comments mainly through two channels: proposed rules and petitions.

Proposed Rules

When FDA plans to issue a new regulation or revise an existing one, it places an announcement in the *Federal Register* on the day the public comment period begins. Published every weekday, the *Federal Register* is available at many public libraries and colleges, and even on the Internet. Issues open to public comment often are reported by the news media and may frequently be found on FDA's Internet home page. (See box.)

Using the Internet

Though the *Federal Register* is readily available from libraries in printed form, it also can be accessed through the Internet's World Wide Web. Two URLs—uniform resource locators, or Web "addresses"—will work:

- *http://www.access.gpo.gov/su_docs/*
- *http://thorplus.lib.purdue.edu/gpo/*

Citizens also can learn about new FDA issues that are open for public comment through the agency's News Page on its World Wide Web site: *http://www.fda.gov/opacom/hpnews.html.*

In the *Federal Register,* the "notice of proposed rulemaking" describes the planned regulation and provides background on the issue. It also gives the address for submitting written comments and the name of the person to contact for more information.

Also noted is the "comment period," which specifies how long the agency will accept public comments. Usually, the file—or docket—stays open for comments at least 60 days, though some comment periods have been as short as 10 days or as long as nine months. Weekends and holidays are included in the comment period.

There is no special form to fill out for comments, nor do submitters have to follow a certain style. But FDA can process comments more effectively if they are presented—either written legibly or typed—on 8½-inch by 11-inch paper.

Here are some other suggestions for making sure your comment has the greatest possible impact:

- Clearly indicate if you are for or against the proposed rule or some part of it and why. FDA regulatory decisions are based largely on law and science, and agency reviewers look for reasoning, logic, and good science in comments they evaluate.
- Refer to the docket number, listed in *Federal Register* notice.
- Include a copy of articles or other references that support your comments. Only relevant material should be submitted.
- If an article or reference is in a foreign language, it must be accompanied by an English translation verified to be accurate. Translations should be accompanied by a copy of the original publication.
- To protect privacy when submitting medical information, delete names or other information that would identify patients.
- Threats, obscenities, profanities, or material defamatory to FDA or the federal government may be rejected or referred to law enforcement officials.
- Comments must be postmarked or delivered in person by the last day of the comment period.

When FDA receives a comment, it is logged in, numbered, and placed in a file for that docket. It then becomes a public record and is available for anyone to examine in FDA's reading room (Room 123, 12420 Parklawn Drive, Rockville, Md.). Under the Freedom of Information Act (FOIA), visitors to the reading room can receive free copies of comments up to 50 pages if their request is for noncommercial use. After that, each page costs 10 cents. People also