DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

June 19, 2007

To: Owners and operators of registered medical device establishments

Re: Postponement of annual registration of all registered medical device establishments

This is to inform you that FDA is postponing the annual registration of your registered medical device establishment. This is a temporary action. FDA expects to resume annual registrations in October or November 2007. If your establishment is registered for 2007, then your registration will remain valid until December 31, 2007.

FDA is taking this action because upcoming changes may significantly change the way you register your establishment and list your devices. Among the changes that may take place during the next several months are:

1. Electronic registration and listing. Section 510(p) of the Federal Food, Drug, and Cosmetic Act permits FDA to require registration of medical device establishments "by electronic means" once FDA has determined "the electronic receipt of such registrations is feasible." FDA will soon announce that we have made that determination. We are also working hard to complete and publish a proposed regulation to implement electronic registration of medical device establishments and electronic listing of the medical devices that are produced or processed by those establishments. Electronic registration and listing will provide benefits for both FDA and you —

- It will be quicker and easier. It will avoid mistakes (which currently occur about 1/3 of the time), because error-checking is built-in.
- The enhanced accuracy and accessibility of the system would allow us to reduce your mandatory review and update of listing information to just once a year, instead of twice. This change will require Congressional approval, and FDA expects it will be among the statutory changes Congress will consider later this year (see item 4).
- Establishments will no longer have to research and enter product code information for non-exempt medical devices, because the electronic system will provide the correct product codes automatically.
- You will have 24/7 access to update or make changes on your own schedule.
- The electronic system will allow listing of more than one proprietary name for a given product.
- Because of its improved accuracy and timeliness, your listing data will be more useful to hospitals, health care professionals, and others who are trying to find sources for particular types of devices.

2. Simpler registration and listing requirements. In conjunction with our planned transition to electronic registration and listing, FDA is working to complete a proposed revision of its regulations governing medical device establishment registration and medical device listing, 21 C.F.R. Part 807. We expect this revision will make our requirements easier to understand, and will provide you greater flexibility in describing the devices you list. You will have an opportunity to provide comments and suggestions later this year when FDA formally proposes these changes in a Federal Register notice.

3. FDA will implement the Bioterrorism Act. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188, the "Bioterrorism Act") requires each foreign establishment to provide, as part of its registration, the name of each known importer of the establishment's devices and the name of each person who imports or offers to import the device into the United States. FDA's revision of its registration and listing regulations will help foreign establishments meet this statutory requirement.

4. Congress will consider new legislation that may affect registration and listing. As directed by section 105 of the Medical Device User Fee and Modernization Act of 2002, FDA is actively developing recommendations to the Congress for the goals and plans for meeting the goals for the process for the review of medical device applications beginning fiscal year 2008, and for the reauthorization of the user fee sections of the Federal Food, Drug, and Cosmetic Act. As an essential part of this process, we are consulting with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry. Although those consultations are still underway, FDA expects some of our recommendations to Congress, if adopted, may affect our medical device registration and listing requirements.

For these reasons, we believe it is in the best interest of both FDA and industry to postpone the annual registration of currently-registered medical device establishments until we have greater certainty concerning requirements that may go into effect in the coming months. FDA believes this action will reduce burdens and costs on your establishment by avoiding the potential need for you to re-submit registration and listing updates later this year. Instead, you will register and complete a review and update of your listing information only once this year, and only after any changes have been put into effect.

FDA expects to have new systems in place before the end of the year, and FDA will ensure you have ample time to renew your establishment's registration before it expires.

We will continue to register new establishments for calendar year 2007. All new establishment registrations will expire December 31, 2007.

We will provide updated information on our web site (www.fda.gov/cdrh) over the next several months, and we will write to you again when we resume annual establishment registrations to inform you of any new procedures or requirements. If you have any questions, please call 240-276-0111 or send an email to device.reg@fda.hhs.gov.

Center for Devices and Radiological Health