

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

3/11/92

Food and Drug Administration
Rockville MD 20857

Dear:

We have received your letter requesting FDA policy on exhibiting medical devices prior to FDA marketing clearance.

A firm who has a premarket notification (510K) on file with FDA pending premarket clearance may display the device but may not take orders or be prepared to take orders that might result in contracts of sale for the device.

Since the devices to be shown have not yet been cleared for marketing by FDA, it may be possible for the importer or importer's agent to enter into an agreement with FDA permitting release of the entry for the sole purpose of exhibit at the trade function. Once the exhibit has ended, you are required to destroy or re-export the devices or designate an agent to do so.

Also, FDA recommends using placards during the exhibit at the point of display, advising that the exhibited products cannot be sold since they are not in full compliance with applicable FDA regulations.

The FDA district office where the exhibition is to be held should be contacted if you need information. If you need the name and number of a specific district office or if you need additional information on complying with FDA regulations, our phone number is 301-443-6597 and our fax number is 301-443-8818.

The aforementioned FDA policy on exhibiting devices that do not have marketing clearance is currently being reconsidered. If the policy changes over the next several months, I will fax a copy of the new policy to you for your consideration.

Sincerely yours,