



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

**ADVANCED MICRODEVICES PVT. LTD.**

Attn: Mr. Vivek Singh  
Management Representative  
20-21, Industrial Area  
Ambala Cantt.- 133006  
India

Dear Sir/Madam:

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

**DMF Number Assigned:**15554 **Date of Submission:** July 26, 2001

**DMF Type:** V

**Title of Submission:** Membrane Disc Cartridge Filters Used of Sterilisation fo Drug Products **as manufactured in India**

**Holder of Submission:** Advanced Microdevices Pvt. Ltd.

**Submitted by:** Advanced Microdevices Pvt. Ltd.

**Agent (s):** none

All subsequent correspondence to this DMF should be identified with the information as provided above. Submissions to DMF should be forwarded in duplicate.

Your DMF will be reviewed only in connection with the New Drug Applications, Abbreviated New Drug Applications, Investigational New Drug Applications or any DMFs it is intended to support.

The holder of the DMF is responsible for compliance with the Regulation Title 21 Code of Federal Regulations Part 314.420 as interpreted in "The Guideline for Drug Master Files" [HEW (FDA) 79-3072]. This information can be found at [www.fda.gov/cder/guidance/index.htm](http://www.fda.gov/cder/guidance/index.htm). This includes adhering to the statement of the commitment and providing the FDA with the following:

- an annual list of all individuals and firms authorized to make reference to the DMF and identification of any party whose authorization has been withdrawn;
- an annual update of the DMF or a statement that the DMF remains current (which ever is appropriate); and
- amendments which incorporate any changes in the DMF. Parties authorized to reference the DMF should be notified of the changes before implementation.

Sincerely,

Angela Williams  
Technical Information  
Division of Data Management & Services  
Records Management Team

CC:Chron  
DMF 15554 Orig.,Dup.