



Food and Drug Administration
Rockville MD 20857

FILE COPY

October 05, 2001

Sanford Lewis
Health Care Without Harm
371 Moody St Suite 110
Waltham MA, 02453

Dear Mr. Lewis:

Your petition, submitted on behalf of Health Care Without Harm, requesting the Food and Drug Administration to reconsider the decision regarding Reg/Guide to Label Medical Devices contain'g Phthalate Plasticizers on September 5, 2001, was received by this office on 10/05/01. It was assigned docket number 99P-2077/PRC 1 and it was filed on 10/05/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie C. Butler

Jennie C. Butler
Dockets Management Branch

99P.2077

ACK 2