DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

November 14, 2013

Terry L. Tennant
(b) (6)
[redacted]

Dear Petitioner:

Your petition to the Food and Drug Administration requesting the Agency to change the definition of a Distributor in 21CFR 804.3(d) and other locations in 21CFR to assure patient safety in applying QSR requirements to all marketing of any device sold in the United States, was received by this office on 10/17/2013. It was assigned docket number FDA-2013-P-1373/CP1, and it was filed on 11/14/2013. 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,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)