

Food and Drug Administration Rockville MD 20857

December 11, 2013

FILE COPY

David Trump, Ph.D. Spectron mrc, LLC 17490 Dugdale Drive South Bend, IN 46635

Re: This is a correction to the acknowledgement letter of 12/2/2013

Dear Dr. Trump:

Your petition to the Food and Drug Administration requesting the Agency to issue a notice that Sodium Pertechnetate Tc-99m (technetium Tc-99m sodium pertechnetate) was not withdrawn from sale for reasons of safety or effectiveness was received by this office on 11/21/2013. It was assigned docket number FDA-2013-P-1516/CP1, and it was filed on 12/2/2013. 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

Director

Division of Dockets Management

Keren Kennach

FDA/Office of the Executive Secretariat (OES)