PDA
Parenteral Drug Association

Connecting People, Science and Regulation®

PDA Global Headquarters
Bethesda Towers
4350 East West Highway
Suite 150
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
www.pda.org

September 13, 2013

Division of Docket Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Reference: FDA Proposed Rule21 CFR Parts 1 and 16 Administrative Detention of Drugs Intended for Human or Animal Use
[Docket No. FDA-2013-N-0365]

Dear Sir/Madam,

PDA appreciates the opportunity to comment on this proposed rule. PDA supports FDA's efforts to better protect the integrity of the drug supply chain through implementation of the FDASIA provisions.

PDA attached comments are in two areas. In order to increase transparency, PDA requests that the final rule include clarification of how the FDA will work with foreign governments to address concerns noted at non US sites. In addition, PDA suggests clear language regarding notification of the termination of the detention period.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments were prepared by a committee of experts with experience in pharmaceutical manufacturing including members representing our Board of Directors and our Regulatory Affairs and Quality Advisory Board.

If there are any questions, please do not hesitate to contact me.

Sincerely,

Richard Johnson,
President, PDA

CC: Rich Levy, PDA; Denyse Baker, PDA

Administrative Detention of Drugs Intended for Human or Animal Use; 21 CFR Parts 1 and 16
Food and Drug Administration Proposed Rule
Sept 13, 2013

Line No.	Current Text	Proposed Change	Rationale
Purpose of the Regulatory Action	FDA already has the authority to administratively detain devices, tobacco, and foods that FDA has reason to believe are adulterated or misbranded.	Add the following: "If FDA determines drugs manufactured at a non U.S site may be adulterated or misbranded, FDA will notify and cooperate with the appropriate local health authority to ensure protection of the public health through notification in the spirit of international cooperation."	The preamble to the final rule should highlight the intent to collaborate with foreign governments in protecting the common public health. If possible, FDA should denote the manner in which it will work with foreign governments to address how detention authority may be applied in a coordinated manner to address concerns noted at foreign facilities. Including this language in the preamble to the final rule aligns to agency goals in increasing policy transparency and demonstrates to the public that agency efforts will be applied to foreign manufacturers when safeguarding the quality of the U.S. drug supply.
Part (j) Detention Termination	*If FDA decides to terminate a detention or when the detention period expires, whichever occurs first, an FDA representative authorized to terminate a detention will issue a detention termination notice …*	Insert the following clause: "…an FDA representative authorized to terminate a detention will notify the person who received the original detention order or that person's representative of the detention termination by telephone or other means of rapid communication and then issue a written detention termination notice … "	After waiting 20 – 30 days, the manufacturer should not be additionally delayed in processing the drugs while waiting for the written detention termination notice. Rapid notification is key to minimizing potential risk to patients caused by a delay in the availability of product. For short shelf life products a matter of days can have a significant impact on ability to maintain the highest standards in product quality.