ANIMAL HEALTH INSTITUTE
Representing manufacturers of animal health products

Samata Veluvolu
Manager, Regulatory Affairs

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

Re: Docket No. FDA–2013–D–0710; Draft Guidance for Industry on Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments to Docket No. FDA–2013–D–0710; Draft Guidance for Industry on Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection**.** AHI is the national trade association representing manufacturers of animal health products -- the pharmaceuticals, biological products and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. AHI member companies represent the majority of animal pharmaceuticals and animal insecticides, as well as serving a significant segment of the world market.

Please see the attached table for specific comments and recommendations on the draft guidance.

Thank you in advance for your consideration of these comments. Should you have any questions, please do not hesitate to contact AHI at (202) 637-2440.

Sincerely,

Samata Veluvolu

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Manager, Regulatory Affairs

1325 G Street, NW ■ Suite 700 ■ Washington, D.C. 20005-3104
Telephone (202) 637-2440 ■ Fax (202) 393-1667
www.ahi.org

				Document: Draft Guidance for Industry on Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection
Commenter	**Page No.**	**Line(s)**	**Current Text**	**Comments/Recommendations**
AHI	Page 2	Lines 67-81	A. Delay Scheduling Pre-announced Inspections While not required by the FD&C Act, FDA may (and often does) contact a facility's management in advance and pre-announce an inspection. This pre-announcement is intended to facilitate the inspection process and ensure that appropriate records and personnel will be made available. Generally, for drug products, pre-approval and pre-license inspections, and most inspections of foreign facilities are scheduled before an investigator arrives at the inspection site. FDA efforts to schedule pre-announced inspections include sending correspondence to the facility's management, including the facility's U.S. agent, if the facility is a foreign facility. FDA's goal is to contact facilities within a reasonable time prior to the proposed start date of the inspection. FDA will make reasonable accommodations for local conditions, such as weather or security situations, holidays, and other non-work days, and scheduled manufacturing campaigns. Examples of delay in scheduling a pre-announced inspection that may cause drugs to be adulterated under section 501(j) of the FD&C Act include, but are not limited to…	AHI Recommendation: Language regarding pre-approval inspections and the ability to reschedule PAI needs to be in the document. Example Situation: A site is scheduled for a pre-approval inspection, but the required equipment doesn't arrive in time to fully qualify it by the agreed upon inspection date. A site with uninstalled or unqualified equipment for a new product process is automatically considered "not approvable". We need to retain the ability to reschedule the PAI when such unforeseeable events happen without putting all products manufactured at the site at risk of being considered "adulterated".

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AHI	Page 4	Lines 112-123	C. Delay Producing Records A critical aspect of FDA's preparation for inspection and inspection of drug facilities is the review and collection of hardcopy and electronic records, files, and papers bearing on whether the drugs are adulterated, misbranded, or are otherwise in violation of the FD&C Act. For example, records may need to be collected to document evidence of deviations, interstate commerce, product labeling and promotion, and to identify the party or parties responsible for a variety of actions. Although FDA recognizes that facilities require a reasonable amount of time to produce records requested, especially if the records are maintained at a different site, a delay in producing records to FDA without reasonable explanation may be considered delaying the inspection. Examples of delays in producing records that may cause drugs to be adulterated under section 501(j) of the FD&C Act include, but are not limited to…	AHI Comment: With regards to "reasonable time" to obtain records for review - "reasonable" seems to vary from inspector to inspector. Sponsors have seen inspectors complement sites for their retrieval time while other investigators criticize that same site for delaying retrieval, even though the site operated the same in both inspections. AHI is concerned the term "reasonable" is unquantifiable and interpreted differently from inspector to inspector. AHI Recommendation: There needs to be a more precise definition of the permitted time prior to deeming products adulterated
AHI	Page 5	Lines 185-191	C. Limiting Access to or Copying of Records As explained in section III.C, the ability to access and copy records is a critical aspect of FDA inspections. Not allowing an authorized representative of the FDA access to or copying of records that FDA is entitled to inspect by law, including not providing records that FDA requests pursuant to section 704(a)(4) of the FD&C Act, may be considered limiting an inspection. Examples of records limitations include, but are not limited to…	AHI Comment: Regarding the full provision of documents, the FDA has to make an attempt to ensure that they have received all the documents they have requested. During foreign inspections, sometimes the language barrier (even with a translator) doesn't always allow the site to recognize a document or documents have been requested. The inspector should remind the site if a document that has been requested is not provided. If the site somehow overlooks the provision of a document, we consider that reminder to be reasonable prior to determining the product is "adulterated".