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Re: Docket No. FDA–2013–N–1430; Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics; Availability

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments to FDA–2013–N–1430; Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics**.** 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Please see the attached table for specific comments and questions on the draft guidance.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				Document: Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics
Commenter	**Page No.**	**Line(s)**	**Current Text**	**Comments/Questions**
AHI	3	101-102	For prescription and over-the-counter new animal drugs, the applicant must submit at the time of initial dissemination one set of specimens of mailing pieces and other labeling.	We suggest adding "all" before the word "prescription" to read: *For **all** prescription and over-the-counter new animal drugs, the applicant must submit at the time of initial dissemination one set of specimens of mailing pieces and other labeling.** *Please note that Form 2301 requests 2 sets of specimens and should be updated to reflect the requirements.
AHI	5	195-199	FDA recommends that a firm submit to the Agency on Form FDA 2253 or Form FDA 2301 specimens of the interactive promotional media being used on the firm-owned or firm-controlled venue (e.g., blog, message board, or chat room), as described below in Section V. FDA recognizes that firms may be submitting both firm-generated and independent UGC on Form FDA 2253 or Form FDA 2301 as both firm-generated and independent UGC may be dispersed throughout the interactive promotional venue.	We would like clarity on what constitutes a specimen – is FDA looking for screenshots or links?
AHI	6	218-220	At the time of initial display, a firm should submit in its entirety all sites for which it is responsible on Form FDA 2253 or Form FDA 2301. For example, the firm should submit the comprehensive static product website with the addition of the interactive or real-time components.[7] [7] It is preferable for the firm to submit the interactive or real-time communications in an archivable format that allows FDA to view and interact with the submission in the same way as the end user (e.g., working links). Alternatively, firms should submit screen shots or other visual representations.	What is the desired format for something that is "archivable" and able to be viewed the "same as the end user"?
AHI	6	246-249	Once every month, a firm should submit an updated listing of all non-restricted sites for which it is responsible or in which it remains an active participant and that include interactive or real-time communications. Firms need not submit screenshots or other visual representations of the actual interactive or real-time communications with the monthly updates.	Once every month is excessive for animal health. We propose quarterly unless there is a change to a site or additional or deletion of sites.

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AHI	6	253-254	Multiple sites and the corresponding documents can be submitted with a single Form FDA 2253 or Form FDA 2301.	Is the firm required to submit one form for each site or a Form FDA 2301 for every single product on the site? If submissions are for the site and not individual NADA numbers, what NADA number should a firm use?
AHI	7	258-259	The appropriate FDA center (CDER, CBER, or CVM) should be informed via general correspondence on the first day the firm ceases to be active on a site.	We propose changing "on the first day" to "within 30 days of the firm ceasing to be active on a site" to read: *The appropriate FDA center (CDER, CBER, or CVM) should be informed via general correspondence* ***within 30 days of the firm ceasing to be active on a site****.*
AHI	7	261-263	4. However, if a site has restricted access and, as such, FDA may not have access to the site, a firm should submit all content related to the discussion (e.g., all UGC about the topic), which may or may not include independent UGC, to adequately provide context to facilitate the review.	We suggest changing "may" to "does" to read: *4. However, if a site has restricted access and, as such, FDA* ***does*** *not have access to the site, a firm should submit all content related to the discussion (e.g., all UGC about the topic), which may or may not include independent UGC, to adequately provide context to facilitate the review.*
AHI	7	263-265	Screenshots or other visual representations of the actual site, including the interactive or real-time communications, should be submitted monthly on Form FDA 2253 or Form FDA 2301.	Once every month is excessive for animal health. We propose quarterly unless there is a change to a site or addition or deletion of sites.