THE INTERNATIONAL ALOE SCIENCE COUNCIL

IASC Member Update

FDA's Proposed Rule Anticipated to Have Minimal Impact on Aloe Vera Trade; IASC Solicits Data From Members

July 9, 2008 – The U.S. Food and Drug Administration (FDA) published a notice of proposed rulemaking in the June 19 *Federal Register* that is relevant to the use of Aloe vera as an active ingredient in two classes of over-the-counter drugs.[1]

The proposed rule continues a process FDA began in 1972 to address a concern that the agency lacked efficacy data on a significant number of active ingredients being used in OTC drugs. Since 1972, the ingredients identified at the start of the process have been reviewed in batches. For each ingredient under review, FDA asks industry for data to support the use of the substance as an active ingredient in certain types of OTC drugs.[2]

A review of Aloe vera as an active ingredient in topical analgesic drug products and topical antimicrobial drug products was part of a review announced in December 2003. FDA received no data from industry or any other party to support the use of Aloe vera as an active ingredient in these topical drug products. Given the absence of data, FDA published the June 20 proposal that would make the use of Aloe vera as an active ingredient in analgesic and antimicrobial topical OTC drug products unlawful.

This proposed rule does not comment on Aloe vera as an *in*active ingredient in these two classes of topical OTC drugs.

I have spoken to several Board Members, and we have not been able to identify a product affected by the proposed rule. IASC believes at this time that the impact of this rule on the aloe trade will be insignificant. However, the association would like to hear from any member company if it does supply Aloe vera for use as an active ingredient in an OTC drug product that is regulated under the antimicrobial or analgesic topical monographs.[3]

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[1] The complete June 19 *Federal Register* notice may be accessed here: http://www.fda.gov/OHRMS/DOCKETS/98fr/E8-13826.pdf

[2] The complete list of ingredients that have been reviewed since 1972 is available here: http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=310&SECTION=545&TYPE=TEXT

[3] To read FDA's description of the regulation of OTC drugs and for a definition of an OTC drug monograph, please go here: http://www.fda.gov/cder/Offices/OTC/reg_mechanisms.htm#monograph

Additionally, please keep in mind that this is a proposed rule and is not yet final. If you have excellent efficacy data on the use of Aloe vera as an antimicrobial or analgesic agent, IASC requests you send it to us immediately so the association can prepare a submission to FDA.

Comments on the proposed rule and the economic impact of this proposed rule are due to FDA by Sept. 17, 2008.

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