Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 20, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: AMS Health Sciences, LLC – RECALL [Drug]

AFFECTED PRODUCT: **Saba Shark Cartilage Complex**

SUMMARY: **Unclassified Recall; The recall is due to possible contamination of *Salmonella*.**

This product is packaged in black screw-top bottles with the brand name "saba" in red letters, the product name "shark cartilage complex" in white letters, and a net quantity statement of "500 mg 60 capsules" in small white letters. Product from the affected lot can be identified by the Lot Number 416349 and an expiration date of 08/16, both of which are printed in black letters inside a white rectangle that is adjacent to the products "Suggested Use" instructions.

Product from this lot was sold to consumers nationwide through the internet site www.sabaforlife.com during the period of February through August 2014.

SUGGESTED ACTION: **For consumer inquiry only. Any consumer who purchased product with the lot number and expiration date above should dispose of it immediately and may request a refund by calling (866) 758-7222, Monday through Friday, 9:00 am – 5:00 pm (Central).**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

AMS Health Sciences, LLC Issues Voluntary Recall of Saba Shark Cartilage Complex, 60 Capsule Bottles Due to Possible *Salmonella* Contamination

Contact:
Consumer:
866-758-7222
damenndral@amsmainline.com

FOR IMMEDIATE RELEASE — October 17, 2014 — Oklahoma City, Oklahoma — AMS Health Sciences, LLC is notifying the public that it is recalling 2014 bottles of Saba Shark Cartilage Complex due to possible contamination of *Salmonella*, an organism which can cause serious and sometimes fatal infections in young children frail or elderly people, and others with weakened immune systems. Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis and arthritis. To date, no illness or complaints have been reported to AMS Health Sciences, LLC.

A single lot of Saba Shark Cartilage Complex is the subject of this public announcement and recall as a result of a sample from one bottle that tested positive for *Salmonella*. This product is packaged in black screw-top bottles with the brand name "saba" in red letters, the product name "shark cartilage complex" in white letters, and a net quantity statement of "500 mg 60 capsules" in small white letters. Product from the affected lot can be identified by the Lot Number **416349** and an expiration date of **08/16**, both of which are printed in black letters inside a white rectangle that is adjacent to the products "Suggested Use" instructions.

Product from this lot was sold to consumers through the internet site www.sabaforlife.com during the period of February through August 2014. AMS is initiating this recall out of caution for consumer health, even though numerous samples from the same Lot No. have tested negative for *Salmonella*.

Any consumer who purchased product with the lot number and expiration date above should dispose of it immediately and may request a refund by calling (866) 758-7222, Monday through Friday, 9:00 am – 5:00 pm (Central). If you have consumed the product and are experiencing any unusual or severe symptoms such as those described above, go to an emergency room immediately or contact your physician for immediate advice.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm, or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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