DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

February 18, 2010

John S. Eldred
Keller & Heckman
222 Yan'an Dong Lu
The Bund Center, Suite 3604
Shanghai, 200002
People's Republic of China
Email: eldred@khlaw.com

Re: Food Contact Substance Notification FCN 000963

Dear Mr. Eldred:

This letter acknowledges your notification (FCN 000963), received on January 11, 2010 and amended on February 9, 2010, submitted on behalf of Zhejiang Hisun Biomaterials Co. Ltd. for the food contact substance and its use/limitations described as follows:

Food Contact Substance (FCS)
(3R,6R)-3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione (CAS Reg. Nos. 9051-89-2) (aka polylactide polymers), manufactured and characterized as described in the notification.

Intended Use
As components of food-contact articles.

Limitations/Specifications

The finished polymers are intended to contact all food types under Conditions of Use B through H, as described in Table 2, which can be accessed from the Internet in the Food Ingredients and Packaging section under the Food topic of www.fda.gov.

If we do not object to your notification prior to May 11, 2010, the notification will become effective on that date. Should the notification become effective, it would apply only to the FCS whose manufacture, identity, specifications and conditions of use conform to the information submitted in the notification and upon which the determination of safety is based.

If your notification becomes effective, it will be added to the list of effective notifications and your environmental record will be made publicly available. These can be accessed from the Internet in the Food Ingredients and Packaging section under the Food topic of www.fda.gov.

The above description will be used by FDA to describe your notification should it become effective. Accordingly, please review the description for technical accuracy, review the environmental assessment for confidential information, and provide us with any comments within 30 days from the date of this letter. If your comments result in changes to the identity or intended use of the substance, FDA will evaluate whether the changes affect the adequacy of information in your original FCN. If that adequacy is affected, the agency will request additional information to support the changes in identity or intended use. A new 120-day statutory time period will begin the date we receive the requested information.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Vanee Komolprasert, Ph.D., P.E.
Consumer Safety Officer
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition