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November 9, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
<http://www.fda.gov/dockets/ecomments>

Re: Unique Device Identification; Request for Comments [Docket No. 2006N-0292]

Dear Sir/Madam:

The following comments are offered in response to the invitation to comment about specific UDI issues for medical devices. Our comments reflect issues related to the use of UDI for contact lenses classified by FDA as Class II and Class III Medical Devices. The comments are directed to some of the specific questions presented in the Federal Register Notice of August 11, 2006. For questions not addressed in this letter, Vistakon has no comment on that particular question.

In regard to questions 1 and 2, development of a unique device identification system is influenced by the device itself as well as the user requirements. Given the range of devices and user requirements, any guidance by FDA in development of a system for the use of UDIs for medical devices should allow for device specific elements. This would best be implemented as a voluntary system.

In regard to questions 5 and 7, we have implemented UDI for our product line. We have a Lot Number and UPC that are both bar code and human readable. Our level of packaging (unit of use) for the UDI is the carton (containing 6, 12, or 30 contact lenses). Each individual carton is identified by a trail code added to the lot number. Comparing our product line to other types of medical devices, we recognize that what works for us is not universally applicable, and we support the position that the level of packaging be based on the type of device. The carton level does not work for all devices anymore than trying to put a UDI directly on a contact lens does not work for us.

We appreciate this opportunity to express our comments for consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Courtney", is written over a horizontal line.

Richard C. Courtney, O.D.
Sr. Manager, Regulatory and Clinical Affairs