July 18, 2016

Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: [Docket No. FDA-2016-D-0271] Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

Dear Dr. Califf,

On behalf of the more than 13,500 U.S. members of the American Academy of Dermatology Association (AADA), I appreciate the opportunity to provide input to the Food and Drug Administration (FDA) in response to its draft guidance on Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry. The Academy is committed to excellence in medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology and dermatopathology; and supporting and enhancing patient care to reduce the burden of disease.

The AADA appreciates the FDA proposing to allow anticipatory compounding and distribution by hospital pharmacies. However, we find that the 1-mile radius is inadequate and arbitrary, especially where the hospital pharmacy compounds for its satellite offices. For example, hospital pharmacies may prepare buffered lidocaine for dermatology clinics including those further than one mile.

Many hospital pharmacies buffer lidocaine in large volumes for distribution and administration that same day. For example, one academic medical center pharmacy’s dermatology department administers an average of 250 lidocaine syringes daily for biopsies, skin cancer excisions, and other dermatologic procedures. The lidocaine syringes are distributed prior to receipt of a patient-specific prescription and administered after the order is written in the patient chart.
Because the FDA is concerned about patient safety, the AADA recommends having meaningful criteria for distribution of anticipatorily compounded drugs by hospital pharmacies. We ask that the FDA consider using the beyond-use date (BUD), which is the date after which a compounded drug should not be administered. This date is determined when the drug is compounded.

The AADA appreciates the opportunity to provide comments on this FDA draft guidance on hospital and health system compounding. Please contact Natasha Pattanshetti, JD, MPH, Manager of Regulatory Affairs at npattanshetti@aad.org or (202) 712-2618 if you require clarification of any of the comments in this letter or would like more information.

Sincerely,

Abel Torres, MD, JD
President, American Academy of Dermatology Association

CC: Elaine Weiss, JD, Executive Director
    Barbara Greenan, Senior Director, Advocacy and Policy
    Leslie Stein Lloyd, JD, Director, Regulatory and Payment Policy