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ALLERGY PRODUCTS CONTRACT MANUFACTURING
HollisterStier LABORATORIES LLC

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December 1, 2006

Food and Drug Administration
Division of Dockets Management
HFA-305
5630 Fishers Lane - Room 1061
Rockville, MD 20852
Fax: (301) 827-6870

Re: Docket No. 2005N-0403 - NDC Numbers
Comments for Public Meeting – December 11, 2006

Dear Sir/Madame:

Hollister-Stier Laboratories is submitting the following comments for consideration at the December 11, 2006 public meeting. We realize that this information is being submitted after the November 24th deadline, but are hopeful that it will be added to the agenda.

Hollister-Stier is a manufacturer of Allergenic Extracts, as well as a contract manufacturer of parenteral drugs and biologics.

The Allergenic Product business can be divided up into 3 product groups:

i. Single Antigen and Stock Mixtures comprised of:
- *Diagnostics*
  - Scratch, Prick/Puncture
  - Intradermal
- *Therapeutic bulks*
  - Multiple finished good (F.G.) sizes
  - Typically consists of the strongest extract strength or strengths

ii. Custom Formulations (For the physician's practice)
- *Custom combinations of allergens*
- *Custom Strengths*
- *Choice of F.G. size*

iii. Custom Patient Formulations (prescriptions) ordered by a physician and shipped directly to the physician for dispensing to patient
- *Sets of dilutions*
  - 2 or more vials
- *Custom Formulations*
  - Strengths are not standard from set to set
- *Maintenance (Refills)*
  - Custom Formulations
  - Strengths are not standard
  - Choice of vial size

2005N-0403

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Ninety-nine percent of all products (groups i, ii and iii) are shipped directly to physicians or clinics. Rarely are these products handled through distributor/pharmacy networks.

Proposed Rule - part 207.9 and 207.41 state that allergenic extracts must have NDC numbers. Hollister-Stier's BLA's contain some 650 unique allergens and an additional number of "stock mixtures". These allergens are currently represented through only 10 NDC numbers, each defined as "as ordered" (i.e. no specific finished good package configurations listed).

Applicable only to group "i" above, considering the number of allergens in our BLA's and the potential number of finished good package forms, the proposed NDC requirement would result in the necessity to create more than **3500** NDC numbers. In actual practice, we presently manufacture approximately **350** unique allergens. The proposed NDC requirement would mandate the creation of greater than **1000** NDC's.

For groups ii and iii as defined, Hollister-Stier has no idea of how to assign or print NDC numbers to address their infinite combinations of allergens and product forms.

We request that CBER clarify this for us.

Prescription Professional Labeling (PPL), in SPL format, is to be submitted electronically with each NDC. Hollister-Stier utilizes 8 PPL's to address allergen finished good formats. In certain situations, we will have 3 different PPL's to address different finished good forms of the same allergen.

- One for diagnostic scratch test.
- One for diagnostic intradermal test.
- One for the therapeutic bulk.

Another way of looking at this subject would be to say that we will link 350 unique allergens (NDC's) to one scratch test PPI; the same 350 allergens to an intradermal test PPI, and the same 350 allergens to a therapeutic PPI.

The above suggests that we will not be able to group the different product forms under one NDC number with differentiating package configurations. Is this correct?

The above scenario excludes discussion of the Custom Patient Formulation PPI, nor have we formulated questions relative to our Hymenoptera Venom Product line or Standardized Allergenic Extracts.

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In conclusion, we apologize for not submitting this information in a timely manner, but we are hopeful that your responses could be presented in the public meeting. A copy of this letter has been faxed to your department. Thank you for your review of our comments.

Sincerely

David L Mirabell
Director, Regulatory Affairs

tlm