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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Comments on a Proposed Rule

RE: Docket No.2005N-043, RIN 0910-AA49: Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs; Proposed Rule

Dear Sir/Madam:

Greer Laboratories, Inc. hereby submits comments to Docket No. 2005N-043, RIN 0910-AA49 Proposed Rule "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs" Published in the Federal Register on August 29, 2006 and on October 31, 2006, the comment period for this proposed rule was extended to January 26, 2007.

Greer is one the leading manufacturers and distributors of allergenic products (extracts) in the United States. Greer distributes the allergenic extracts directly to allergy specialists - physicians, clinics and hospitals – who use them to diagnose patients and to compound dosage strengths that are appropriate for treating their patients. Greer has CBER licenses for these products. Under the current federal legislation, allergenic extract manufacturers are exempt from user fees and bar coding by PDUFA and section 201.25 of the regulations respectively.

As a U.S. registered GMP manufacturer and licensed distributor of extract products, Greer is fully supportive of the roll of the Food and Drug Administration in protecting the health and safety of patients and FDA's intent to improve the drug registration and listing regulatory provisions. We understand FDA's reasons for proposing the subject rule. It was noted in the Summary section of the proposed rule that FDA feels that the present drug registration and listing regulations need to be clarified and modified because data from these systems is relied on for such programs as postmarketing surveillance (including FDA inspections), bioterrorism, drug shortages and availability, and user fee assessments. Thus in addition to the proposed registration and listing changes, the FDA has also proposed to require National Drug Codes (NDC) on products and require NDC bar coding on products whenever non-NDC bar codes are placed on the product labels. In this letter, Greer is submitting comments on the proposed rule because, in our opinion, when certain provisions of this rule are implemented, they will create an immense and

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unnecessary burden to the FDA, other healthcare manufacturers and Greer and other manufacturers of allergenic extracts. See our following comments on the various provisions of the proposed rule, especially the comments on the NDC coding and Bar Coding provisions.

Greer comments on the proposed rule:

1. The proposed Section 207.9 (c) (1) (iii) lists “Allergenic products” as a product(s) covered by the rule. Greer feels that “Allergenic products” should be removed from the list of products covered by the rule or “Foreign Manufactured Allergenic Extract products” added to this section. The rationale for not including “Allergenic products” in this section is as follows.

Our comments are based on FDA stated need for this rule: 1.) Clarification and modification of current drug registration and listing regulations is needed since the FDA relies on these data for administering programs, such as bioterrorism, postmarketing surveillance (including FDA inspections), drug shortages and availability, and user fee assessments and 2.) Changes needed to NDC and bar coding systems. Our rationale for removing “Allergenic products” as a product covered by this rule is as follows:

- a. If registration, listing and NDC/bar coding data are needed for bioterrorism purposes, the Agency should reword the “Allergenic products” text to read “Foreign Manufactured Allergenic Extracts products”. By wording in such manner, the foreign manufactured allergenic extracts and their products entering the United States would be subject to the full registration, listing and NDC requirements. However, it should be noted that the population of people in the United States taking prescription extracts is small and these products are unlikely candidates for bioterrorism purposes since they also are not prescribed for life threatening diseases and conditions. If there is no concern of these drugs being used for bioterrorism or registration purposes, “Allergenic products” should be deleted from this Section of the rule or perhaps only the new registration and listing provisions be applicable to Allergenic products.
- b. The FDA already has regulations in place for registering U.S. manufacturing facilities, conducting FDA inspections, reporting of Adverse Experiences, requiring drug product listings and bar coding, and assigning labeler codes and NDC numbers. In summary, U.S. allergenic product manufacturers are already registered with FDA; the U.S. manufacturers are inspected periodically by the FDA; when necessary, the medical community, patients and manufacturers submit Adverse Experience reports to the FDA; the U.S. extract manufacturers already submit updated product listings to the FDA annually; have unique NDC numbers assigned to allergenic products (extracts) by product groupings

and cleared by the Center of Biologics; and are exempt from paying user fees by the PUDFA legislation and exempt from bar coding per 201.25 (b)(1)(i)(B). Thus, there is no need to include Allergenic products for the stated FDA reasons for the subject rule. If improvements are being made to the current registration and listing regulations, there may be some logic that the amended drug registration and listing regulations apply to “Allergenic products”.

- c. Greer’s customers like other allergenic product manufacturers are allergy specialists - physicians, clinics and hospitals have no practical need for NDC numbers on the product labels. These entities purchase the extracts directly from Greer. Usually the extracts are ordered by the specialists just prior to depleting their supply or when a specific extract is needed for a patient. When treating a patient, the allergy specialist reads the product labels for specific product information, treats the patient and records the information from the product labels onto patient records. Our customers have no need for NDC numbers when identifying the product, diagnosing, compounding prescriptions for their allergy patients or when inventorying their supplies. Greer does not sell allergenic products to wholesalers or retailers. Furthermore by exempting allergenic extracts from the present 201.25 regulation, the FDA has already acknowledged that there is no need to place bar codes which normally contain the NDC information onto allergenic products as a means to protect the health and safety of allergy patients.
- d. Currently, Greer and the other allergenic product manufacturers have NDC numbers which have been assigned to groupings of allergenic extracts. Greer has 246 assigned NDC numbers. These NDC numbers were cleared by CBER in product groupings such as – 1.) Pollens, 2.) Molds, Rusts and Smuts, 3.) Epidermals, 4.) Foods & Misc. Inhalants, 5.) Insects, 6.) House Dust, etc. See the attached list of Greer allergenic product NDC numbers. The new rule requires the generation of NDC numbers for each product/line item, not by product groupings. If required, CBER and Greer would have to change our existing databases and increase the number of NDC numbers from 246 to ~ 6640 (415 products x 4 product strengths for each product x 4 product fills for product each strength). The present system of NDC numbering by product groups is adequate. Greer sees no added benefit to increasing the number of NDC numbers as a means to protect the health and safety of allergy patients.
- e. Greer estimates that we distribute approximately 6640 product line items (415 products x 4 product strengths for each product x 4 product fills for each product strength). These NDC numbers would have to be assigned by the FDA and the labels revised by Greer. A change to require NDC numbers for each line item could likely result in errors and confusion

between the legacy NDC numbers and the new NDC numbers on the product labels and in the existing databases at the FDA and Greer. Additionally, the FDA has greatly underestimated the burden to carry out this amount of changes to Greer's allergenic product labeling and the labeling of other allergenic manufacturers.

2. In Section 207.13, Greer feels that "Domestic Allergenic Extracts Manufacturers" or "Allergenic Extracts Manufacturers" should be added to 207.13 as being exempt from the registration and listing requirements of the rule.

The rationale to exempt "Allergenic Extract Manufacturers" from this rule is as follows:

- a. "Allergenic Extract Manufacturers" should be exempt from the registration and listing requirements because the FDA already has regulations in place for manufacturers to register and submit drug product listing and updates. Thus, there is no need to include Allergenic products for the stated FDA reasons for the subject rule.
- b. If improvements are being made to the current registration and listing regulations, there may be some logic that "Allergenic products" be subject to the portion of the rule that amends the drug registration and listing regulations.

3. This rule proposes to change Section 201.25 (e) Bar Code Label Requirements by saying that requirements for a bar code do not apply unless code is displayed (on the label). Greer finds this requirement to apply a bar code when the label contains a code to be unacceptable. This requirement should be eliminated from the rule since presently allergenic extract manufacturers can add bar codes on their own volition. The rationale for eliminating this requirement of allergenic manufacturers and other manufacturers to add NDC bar codes when they have bar codes on their labels for inventory purposes is as follows:

- a. Many companies in this industry and other industries place bar codes on the product labels for internal inventory, warehousing and order picking purposes. Where bar codes are applied by the manufacturers for internal purposes only, there should be no requirement to include NDC style bar code if not presently required by the FDA. Where products are presently exempt from bar coding, the placing of NDC style bar codes should remain at the discretion of the product distributors based on customer need and allergenic extracts remain exempt from bar coding.
- b. Greer's customers of allergenic products are allergy specialists - physicians, clinics and hospitals. Our customers are trained to read the product labels and have no need for bar codes when identifying the

product, diagnosing, compounding prescriptions for their allergy patients or when inventorying their supplies. Greer does not sell allergenic products to wholesalers or retailers. Allergenic extracts are presently exempt from the present 201.25 bar code regulation; thus, the FDA has already acknowledged that there is no need for bar coding allergenic products (extracts) in order to protect the health and safety of allergy patients from medication errors.

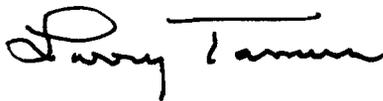
- c. Greer has bar codes for inventory type purposes and our allergenic extracts are presently exempt from having bar codes with NDC information. If NDC style bar code is required, there may be insufficient space on the label to include the NDC style bar code. In this case, the NDC bar code should not be required.
- d. Greer estimates that we distribute approximately 6640 product line items (415 products x 4 product strengths for each product x 4 product fills for each product strength) that would require NDC style bar codes. The FDA has greatly underestimated the burden to carry out the changes to allergenic products and could open up the possibility of labeling errors when carrying out this requirement.

Greer feels that if the subject provisions, primarily the NDC and bar coding requirements, of the rule are implemented as written, there will be immense and unnecessary burden placed on the FDA, Greer, and other domestic manufacturers of allergenic extracts and could result in errors being made by the FDA and the allergenic products manufacturers.

We look forward to the Agency's effort to address Greer's concerns about this rule. We strongly urge you to consider these facts and, in doing so, grant appropriate exemptions for "Allergenic products" from the NDC and bar coding provisions of the proposed rule.

If the FDA has questions on the rationale for our changes to the proposed rule, please contact me at ltamura@greerlabs.com or at (828) 759-7442.

Sincerely yours,



Larry Tamura
Director Regulatory Affairs

NDC Numbers Assigned for Greer Laboratories
 Revised 06/19/00

Item	Strength	Units	NDC Number	Volume
POLLENS	1:10	W/V	NDC 22840-0001	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
POLLENS	1:20	W/V	NDC 22840-0002	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
POLLENS	1:40	W/V	NDC 22840-0003	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
POLLENS	10000	PNU	NDC 22840-0004	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
POLLENS	20000	PNU	NDC 22840-0005	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
POLLENS	40000	PNU	NDC 22840-0006	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
MOLDS, RUSTS AND SMUTS	1:10	W/V	NDC 22840-0007	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
MOLDS, RUSTS AND SMUTS	1:20	W/V	NDC 22840-0008	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
MOLDS, RUSTS AND SMUTS	1:40	W/V	NDC 22840-0009	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
MOLDS, RUSTS AND SMUTS	10000	PNU	NDC 22840-0010	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
MOLDS, RUSTS AND SMUTS	20000	PNU	NDC 22840-0011	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
MOLDS, RUSTS AND SMUTS	40000	PNU	NDC 22840-0012	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML

NDC Numbers Assigned for Greer Laboratories
 Revised 06/19/00

Item	Strength	Units	NDC Number	Volume
EPIDERMALS	1:10	W/V	NDC 22840-0013	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
EPIDERMALS	1:20	W/V	NDC 22840-0014	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
EPIDERMALS	1:40	W/V	NDC 22840-0015	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
EPIDERMALS	10000	PNU	NDC 22840-0016	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
EPIDERMALS	20000	PNU	NDC 22840-0017	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
FOODS & MISC. INHALANTS	1:10	W/V	NDC 22840-0018	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
FOODS & MISC. INHALANTS	1:20	W/V	NDC 22840-0019	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
FOODS & MISC. INHALANTS	1:40	W/V	NDC 22840-0020	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
FOODS & MISC. INHALANTS	10000	PNU	NDC 22840-0021	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
FOODS & MISC. INHALANTS	20000	PNU	NDC 22840-0022	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
INSECTS	1:10	W/V	NDC 22840-0023	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML
INSECTS	1:20	W/V	NDC 22840-0024	-4 5 ML
				-6 10 ML
				-8 30 ML
				-9 50 ML

NDC Numbers Assigned for Greer Laboratories
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Item	Strength	Units	NDC Number	Volume
INSECTS	1:40	W/V	NDC 22840-0025 -4	5 ML
			-6	10 ML
			-8	30 ML
			-9	50 ML
INSECTS	10000	PNU	NDC 22840-0026 -4	5 ML
			-6	10 ML
			-8	30 ML
			-9	50 ML
INSECTS	20000	PNU	NDC 22840-0027 -4	5 ML
			-6	10 ML
			-8	30 ML
			-9	50 ML
HOUSE DUST	1:2	W/V	NDC 22840-0028 -4	5 ML
			-6	10 ML
			-8	30 ML
			-9	50 ML
HOUSE DUST	1:1	W/V	NDC 22840-0029 -4	5 ML
			-6	10 ML
			-8	30 ML
			-9	50 ML
HOUSE DUST	1000	PNU	NDC 22840-0030 -4	5 ML
			-6	10 ML
			-8	30 ML
			-9	50 ML
HOUSE DUST	10000	PNU	NDC 22840-0031 -4	5 ML
			-6	10 ML
			-8	30 ML
			-9	50 ML
HOUSE DUST	20000	PNU	NDC 22840-0032 -4	5 ML
			-6	10 ML
			-8	30 ML
			-9	50 ML
DUST MITE DERMATOPHAGOIDES FARINAE	5000	UNT	NDC 22840-0033 -6	10 ML
			-8	30 ML
			-9	50 ML
DUST MITE DERMATOPHAGOIDES FARINAE	10000	UNT	NDC 22840-0034 -3	5 ML SCRATCH-G
			-6	10 ML
			-8	30 ML
			-9	50 ML
HOUSE DUST MITE D. PTERONYSSINUS	5000	UNT	NDC 22840-0035 -6	10 ML
			-8	30 ML
			-9	50 ML
HOUSE DUST MITE D. PTERONYSSINUS	10000	UNT	NDC 22840-0036 -3	5 ML SCRATCH-G
			-6	10 ML
			-8	30 ML
			-9	50 ML
HOUSE DUST MITE MIXTURE	10000	UNT	NDC 22840-0037 -6	10 ML
			-8	30 ML
			-9	50 ML

NDC Numbers Assigned for Greer Laboratories
Revised 06/19/00

Item	Strength	Units	NDC Number	Volume
FREEZE DRIED POLLENS	1:20	W/V	NDC 22840-0038 -6	10 ML
FREEZE DRIED MOLDS	1:20	W/V	NDC 22840-0039 -6	10 ML
SCRATCH TESTS	1:20	W/V	See -0140 to -0146 below -3	5 ML SCRATCH-G
INTRADERMAL TESTS AQUEOUS	1:1000	W/V	NDC 22840-0041 -4	5 ML
INTRADERMAL TESTS AQUEOUS	1000	PNU	NDC 22840-0042 -4	5 ML
FLEA DIAGNOSTIC	1:100	W/V	NDC 22840-0043 -6 -9	10 ML 50 ML
SCRATCH TESTS SPECIALLY PRICED	1:20	W/V	See -0145 to -0146 below -3	5 ML SCRATCH-G
INTRADERMAL TESTS SPECIAL TREATMENT	1000	PNU	NDC 22840-0045 -4	5 ML
INTRADERMAL TESTS SPECIAL TREATMENT	1:1000	W/V	NDC 22840-0046 -4	5 ML
OAT STEM RUST	1:50	W/V	NDC 22840-0047 -4	5 ML
WHEAT STEM RUST	1:50	W/V	NDC 22840-0048 -4	5 ML
CANARY FEATHERS	1:20	W/V	NDC 22840-0049 -4	5 ML
CANARY FEATHERS	10000	PNU	NDC 22840-0050 -4	5 ML
PARAKEET FEATHERS	1:20	W/V	NDC 22840-0051 -4	5 ML
PARAKEET FEATHERS	10000	PNU	NDC 22840-0052 -4	5 ML
GERBEL EPITHELIA	1:20	W/V	NDC 22840-0053 -4	5 ML
GERBEL EPITHELIA	10000	PNU	NDC 22840-0054 -4	5 ML
HAMSTER EPITHELIA	1:20	W/V	NDC 22840-0055 -4	5 ML
HAMSTER EPITHELIA	10000	PNU	NDC 22840-0056 -4	5 ML
RAT EPITHELIA	1:20	W/V	NDC 22840-0057 -4	5 ML
RAT EPITHELIA	10000	PNU	NDC 22840-0058 -4	5 ML
STOCK MIXES	1:10	W/V	NDC 22840-0059 -4 -6 -8 -9	5 ML 10 ML 30 ML 50 ML
STOCK MIXES	1:20	W/V	NDC 22840-0060 -4 -6 -8 -9	5 ML 10 ML 30 ML 50 ML
STOCK MIXES	1:40	W/V	NDC 22840-0061 -4 -6 -8 -9	5 ML 10 ML 30 ML 50 ML
STOCK MIXES	10000	PNU	NDC 22840-0062 -4 -6 -8 -9	5 ML 10 ML 30 ML 50 ML
STOCK MIXES	20000	PNU	NDC 22840-0063 -4 -6 -8 -9	5 ML 10 ML 30 ML 50 ML

NDC Numbers Assigned for Greer Laboratories
 Revised 06/19/00

Item	Strength	Units	NDC Number	Volume
STOCK MIXES	40000	PNU	NDC 22840-0064	-4 5 ML -6 10 ML -8 30 ML -9 50 ML
PRESCRIPTION SET		MIS	NDC 22840-0065	-5 5 VIALS: SET -7 6 VIALS: SET-2 MAINT VIALS
PRESCRIPTION, MAINTENANCE VIALS		MIS	NDC 22840-0066	-5 5 ML -6 10 ML
STANDARDIZED CAT HAIR	5000	UNT	NDC 22840-0067	-6 10 ML -8 30 ML -9 50 ML
STANDARDIZED CAT HAIR	10000	UNT	NDC 22840-0068	-3 5 ML SCRATCH-G -6 10 ML -8 30 ML -9 50 ML
STERILE DILUENT FOR ALLERGENIC EXTRACTS-NORMAL SALINE	1	ML	NDC 22840-0101	-3 4.0 ML 5-13 -4 4.5 ML 5-13 -5 4.5 ML 5-20 -6 9.0 ML 10-13 -7 9.0 ML 10-20 -8 30 ML 30-20 -9 8.0 ML 10-13 -0 100 ML 100-20
STERILE DILUENT FOR ALLERGENIC EXTRACTS-NORMAL SALINE WITH HSA	1	ML	NDC 22840-0102	-2 1.8 ML 5-20 -4 4.5 ML 5-13 -5 4.5 ML 5-20 -6 9.0 ML 10-13 -7 9.0 ML 10-20 -8 30 ML 30-20 -9 27.0 ML 30-20 -0 100 ML 100-20
STERILE DILUENT FOR ALLERGENIC EXTRACTS-BUFFERED SALINE	1	ML	NDC 22840-0103	-5 4.5 ML 5-20 -7 9.0 ML 10-20 -0 100 ML 100-20
STERILE DILUENT FOR ALLERGENIC EXTRACTS 10% GLYCERO-SALINE	1	ML	NDC 22840-0104	-1 1.8 ML 2-13 -2 1.8 ML 5-20 -4 4.5 ML 5-13 -5 4.5 ML 5-20 -7 9.0 ML 10-20 -8 30 ML -0 100 ML 100-20
SCRATCH TESTS, Pollens	1:20	W/V	NDC 22840-0140	-3 5 ML SCRATCH-G
SCRATCH TESTS, Molds and Smuts	1:20	W/V	NDC 22840-0141	-3 5 ML SCRATCH-G
SCRATCH TESTS, Epidermals	1:20	W/V	NDC 22840-0142	-3 5 ML SCRATCH-G
SCRATCH TESTS, Foods	1:20	W/V	NDC 22840-0143	-3 5 ML SCRATCH-G

NDC Numbers Assigned for Greer Laboratories
 Revised 06/19/00

Item	Strength	Units	NDC Number	Volume
SCRATCH TESTS, Miscellaneous Inhalants	1:20	W/V	NDC 22840-0144 -3	5 ML SCRATCH-G
SCRATCH TESTS, Insects	1:20	W/V	NDC 22840-0145 -3	5 ML SCRATCH-G
SCRATCH TESTS, House Dust	1:2	W/V	NDC 22840-0146 -3	5 ML SCRATCH-G
SCRATCH TESTS, Special Priced, Pollens	1:20	W/V	NDC 22840-0147 -3	5 ML SCRATCH-G
SCRATCH TESTS, Special Priced, Insects	1:20	W/V	NDC 22840-0148 -3	5 ML SCRATCH-G
Standardized Grass Pollen	100,000	BAU/mL	NDC 22840-0069 -3	5 ML SCRATCH-G
			-6	10 ML
			-8	30 ML
			-9	50 ML
Standardized Grass Pollen	10,000	BAU/mL	NDC 22840-0070 -3	5 ML SCRATCH-G
			-6	10 ML
			-8	30 ML
			-9	50 ML
Standardized Grass Pollen Stock Mix	100,000	BAU/mL	NDC 22840-0071 -3	5 ML SCRATCH-G
			-6	10 ML
			-8	30 ML
			-9	50 ML
Standardized Grass Pollen Stock Mix	10,000	BAU/mL	NDC 22840-0072 -3	5 ML SCRATCH-G
			-6	10 ML
			-8	30 ML
			-9	50 ML