**Barr Laboratories, Inc.**

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June 8, 2001

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

RE: Comments on the Draft Guidance for Industry: Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

Upon reviewing the *Draft Guidance for Industry: Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution*, Barr Laboratories, Inc. had the following comments:

I. Section III: B

The Draft Guidance under Section III: B states the following:

> Form FDA 2657 is used by registrants reporting initial listing information for all drugs and biological products in commercial distribution. This form must be submitted within 5 days of beginning the manufacturing or processing of drugs and biological products. (See 21 CFR 207.21 (a) and 21 CFR 207.22 (b).

Here the Draft Guidance appears to indicate that the 2657 form needs to be submitted 5 days after commercial distribution of a given drug product. However, this statement is contrary to the statute and the regulation; neither of which specify such time of initial listing.

Section 510 (j) (1) under the act states:

> Every person who registers with the Secretary under subsection (b), (c), or (d) of this section shall, at the time of registration under any such subsection, file with the Secretary a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name (as defined in section 352(e) of this title) and by any proprietary name) which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution and which he has not included in any list of drugs or devices filed by him with the Secretary under this paragraph or paragraph (2) before such time of registration.

21 CFR §207.21 (a) further clarifies the requirements specified in the act:

> The owner or operator of an establishment entering into the manufacture or processing of a drug or drugs shall register the establishment within 5 days after the beginning of the operation and shall submit a list of every drug in commercial distribution at that time. If the owner or operator of the establishment has not previously entered into such an operation, the owner or operator shall register within 5 days after submitting a new drug application, new animal drug application, medicated feed mill license application, or a biologics license application.

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The submission of form FDA 2656 for initial registration within 5 days after the beginning of a manufacturing or processing operation is required. However, the submission of form FDA 2657 would be required at the time of initial registration if any drug is in commercial distribution or is being manufactured, prepared, propagated, compounded or processed for commercial distribution. In other words, it is not a statutory requirement to submit form FDA 2657 at the time of initial registration provided that the owner or the operator of an establishment does not have any drug in commercial distribution or is not manufacturing, preparing, propagating, compounding or processing any drug for commercial distribution.

In addition, the section 510 (j) under the act further states:

> On or before December 31 of each year every person who owns or operates any establishment in any state engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices shall register with the Secretary his name, places of business, and all such establishments.

Therefore, the statute does not require any drug listing information to be submitted at the time of annual registration (re-registration). On the other hand, the regulation clearly indicates that form FDA 2657 may be submitted by the registrant at his or her discretion any time after the initial registration. The following is stated in 21 CFR §207.30 (a):

> After submitting the initial drug listing information, every person who is required to list drugs under §207.20 shall submit on Form FDA-2657 (Drug Product Listing) during each subsequent June and December, or at the discretion of the registrant when the change occurs, the following information:
>
> > (1) A list of each drug introduced by the registrant for commercial distribution which has not been included in any list previously submitted. The registrant shall provide all of the information required by §207.25(b) for each such drug.

Based on the above discussion, submission of drug listing information for a newly approved drug is not required within 5 days of commercial distribution. However, drug listing information for a newly approved drug must be submitted every June or December, or at the discretion of the registrant when the change occurs.

Therefore, we recommend that the Section III: B of the Draft Guidance be revised to state the following:

**Form FDA 2657 is used by the manufacturers, repackagers and relabelers:**

- **For drug listing of all drugs and biological products in commercial distribution at the time of initial registration of their establishment. The owner or operator of an establishment entering into the manufacture or processing of a drug or drugs shall register the establishment within 5 days after the beginning of the operation and shall submit a form FDA 2657 for every drug in commercial distribution at that time. (See 21 CFR §207.21 (a) and 21 CFR §207.22 (b).)**

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- **For drug and biological products that have subsequently been introduced for commercial distribution and, therefore, have not been previously listed. Drug listing information for such products must be submitted every June or December, or at the discretion of the registrant when the change occurs.**

- **For any changes in the drug listing information for drug and biological products that have previously been listed. Drug listing information for such changes must be submitted every June or December, or at the discretion of the registrant when the change occurs.**

II. Section IV: B

The Draft Guidance under Section IV: B discusses how and when to update product listing information. The Draft Guidance recommends the submission of forms as soon as possible once a change occurs so that the information can be correctly reflected in *the National Drug Code Directory*. However, the Draft Guidance fails to clearly indicate the fact that drug listing updates are not required at any time after the initial listing so long as no changes have occurred. Regarding updates to drug listing, 21 CFR §207.30 (b) clearly states:

> When no changes have occurred since the previously submitted list, no report is required.

Therefore, we recommend that the Section IV: B of the Draft Guidance be revised to add the following statement:

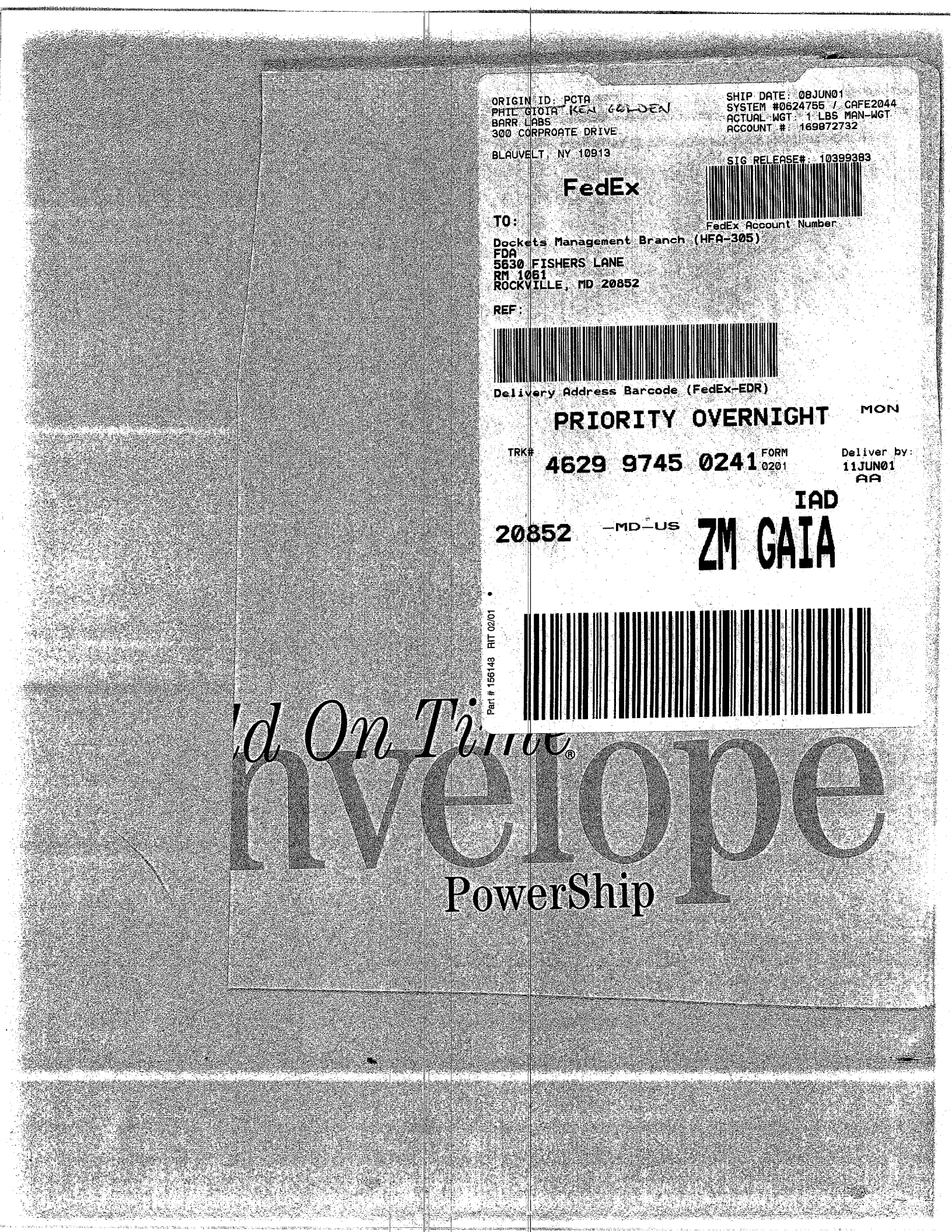
**Submission of form FDA 2657 is not required for a drug when no changes have occurred since the previously submitted list.**

Barr Laboratories appreciates the opportunity to comment on the Agency's Draft Guidance and respectfully submits this evaluation.

Sincerely,

**BARR LABORATORIES, INC.**

Kenneth R. Golden
Regulatory Affairs Associate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BARR LABS
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BLAUVELT, NY 10913
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ACCOUNT #: 169872732
SIG RELEASE#: 10399383
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TO:
Dockets Management Branch (HFA-305)
FDA
5630 FISHERS LANE
RM 1061
ROCKVILLE, MD 20852
REF:
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