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TO:	CC TO:
COMPANY: FDA	COMPANY:
FAX NUMBER: 301-827-6870	FAX NUMBER:

FROM: Adina Tortu

REGARDING:

Docket No. 2005N-0403
Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs

Please see the attached questions and concerns for the Agency regarding the above mentioned proposed new rule.

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The following are questions and concerns that Ranbaxy has regarding the proposed new rule (2005N-0403) to automate drug registration and listing dated August 23, 2006:

1) **NDC (page 19)**
The NDC numbers currently assigned to a drug prior to the effective date of the rule would remain unchanged provided those NDC numbers comply with the new regulations as finalized.

We request FDA to consider the fact that the Agency should extend this to include NDC number's assigned by a firm for products that are still in development and not yet officially listed with FDA. This is because firms often assign NDC number's early on in the development process and use this number on all related documentation and batch records.

2) **Registration (page 191)**
We are proposing to revoke the provision concerning the assignment of a labeler code because the NDC Number requirements would be covered under proposed part 207 and not proposed part 607.

Does this mean that new firms will not be provided a labeler code?

3) **Drug Listing (page 255)**
Under proposed rule 207.57, manufactures, repackers, relabelers, and drug product salvergers must review each June and December all drug listing information that has been provided to the Agency and report all changes or certify that changes have been made.

Does this mean that all changes can only be made during the month of June and December or can changes be made at any time on a rolling basis?

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4) NDC (page 112)
Under proposed rule 207.33(f)(2) requires manufactures to obtain a new NDC number when there is a change in an inactive ingredient for each human prescription drug.

One concern is that FDA is proposing that a change in ingredients would result in the need to assign a new NDC number. We may have two manufacturers for one product. If their inactives don't match, company's are permitted to add a "may also contain" statement to accommodate this. This would no longer be the case. We would need to manage this with two separate inventories for all customers (as many as 40 per product). This is actually one of the more simple scenarios. There are other supply chain relationships that are even more complex.

5) NDC

Is there a minimum number of NDC numbers that a firm can request at one time? How far in advance can a firm request an NDC from FDA?

Will the FDA assign an NDC number to a prescription product which does not have an application number (such as a DESI drug, OTC monograph product or some of the older drugs that still remain in the marketplace)?