TAP PHARMACEUTICAL PRODUCTS INC.

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November 20, 2006

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

RE: Comments on Docket 2005N-0403 and RIN 0910-AA49: 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

TAP Pharmaceutical Products Inc. (TAP) hereby submits comments on Docket 2005N-0403 and RIN 0910-AA49 provided in the enclosed attachment.

Please telephone me at your earliest convenience if I can provide any additional information.

Sincerely,

Jean M. Conaway

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Center for Drug Evaluation and Research (CDER):

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

Proposed Rule: Docket 2005N-0403 and RIN 0910-AA49

1. Proposed Rule Issue:
FDA is proposing a new electronic database to track the NDC listing for drugs on the market and this will replace the current paper system. Sponsors will have nine months to enter all their products into the electronic system after the final regulation takes effect. The electronic system would be available using an internet-based data collection system accessed through the FDA internet site.

TAP Response:
Nine months to implement the new electronic system may not be adequate, based upon a sponsor's existing workload and on the capability of the electronic system to handle multiple users.

2. Proposed Rule Issue:
Electronic updates need to be submitted by sponsors every 6 months for prescription and OTC drugs which includes information on the manufacturing site(s), whether the drugs are still on the market, NDA number(s), etc.

TAP Response:
Confidentiality of proprietary information needs to be assured. The manufacturing site location may not be viewed as public information.

3. Proposed Rule Issue:
FDA will assign all three segments of the NDC product code. (Currently the Agency assigns the labeler codes, while the product and packaging codes are assigned by manufacturers.) The FDA plans to confirm that codes assigned to currently marketed drugs comply with the requirements of the final rule.

TAP Response:
The timing in which the new NDC product code is assigned, the length of the NDC code and whether the code is alpha numeric versus numeric are potential issues for industry. The existing legacy systems may not be able to comply with certain requirements. The timing in which the entire NDC product code is assigned could be an issue for industry in regard to launch preparations and the ability to order components.

4. Proposed Rule Issue:
The proposal would allow electronic systems to reliably and consistently link the NDC number to the appropriate drug labeling through another DHHS health information technology initiative, Structured Product Labeling (SPL).

TAP Response:
Carton, container labeling and physician sample labeling are not a part of the SPL. Paper copies of these labels will still need to be submitted at the time of the biyearly NDC drug listing electronic submissions.

5. Proposed Rule Issue:
Changes in formulation regarding inactive ingredients will require a new NDC number: FDA proposes that the NDC number will change every time an inactive ingredient changes in the formulation. This will enable the FDA to investigate incidents of allergic reactions in patients as well as possible drug contamination, counterfeiting, or adulteration.

TAP Response:
Changes in formulation regarding inactive ingredients can already be tracked through other GMP processes such as product numbers, lot numbers and formula editions applied to master batch records. In order for the NDC number to be an effective tracking tool, it needs to be associated with a bill of materials, which would have to be supplier-specific.

6. Proposed Rule Issue:
Sponsors need to be able to accommodate two NDC numbers for the same drug product/dosage form that have different inactive ingredients/amounts.

TAP Response:
The introduction of new or exchanged excipients already requires a qualification process and a regulatory notification. The method by which pharmaceutical companies currently track excipient usage allows for the efficient retrieval of critical information needed to conduct quality investigations. A change in the NDC numbers at the time the formulations change, does not add any value to the investigation process.

The need to accommodate two NDC numbers for the same drug product and dosage form could cause tremendous work throughout the supply chain. The sponsor would have to notify everyone in the supply chain of the NDC number change. Inventory systems down stream all the way to the pharmacy level would be impacted. In addition, there will be a natural overlap between the old and new NDC numbers for essentially the same product. The supply chain would have to be able to account for both NDC numbers for the same drug product.