February 24, 2006

Alcon®
RESEARCH, Ltd.

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

Re: Docket Number 2005N-0510

Dear Sir or Madam:

Provided herewith are two (2) copies of comments submitted to FDA by Alcon Laboratories, Inc., regarding the Anti-Counterfeit Drug Initiative Workshop held on February 8-9, 2006.

If there are any questions regarding these comments, please contact Garry G. Heidel via telephone at (817) 551-6813, via telefax at (817) 615-3410 or e-mail at garry.heidel@alconlabs.com.

Sincerely:

Garry G. Heidel

Garry G. Heidel
Director Regulatory Compliance
Alcon Research, LTD
Representing Alcon Laboratories, Inc.

2005N-0510

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Alcon Laboratories, Inc. Comments on the Information and Presentations at the February 8-9, 2006 Anti-Counterfeit Drug Initiative Workshop and Vendor Display Docket No. 2005N-0510

Alcon Comments to FDA on Anti-Counterfeiting Initiatives

Alcon strongly supports and applauds Agency efforts to secure the Pharmaceutical supply chain to ensure that only safe and effective drugs reach our patients and consumers.

We attended the recent February 8-9, 2006 FDA Workshop in Bethesda, MD and heard a wide range of opinions regarding this vital issue. The meeting was helpful in learning more about the positions of the various participants in the drug supply chain, but did little to clarify what the problem is, specific actions to be taken, or timing of those actions. The discussions were centered around how to implement technology solutions to problems that were not clearly defined, leading to 'technology solutions in search of a problem'. Clearly, additional dialogue is necessary to gain consensus within the industry on the following key points:

- Defining the problem—what exactly are we trying to accomplish? What does the end-state look like specifically? How do we know that we're on the right track and when we're done?
- Identifying the current and future risks to the drug supply chain from counterfeiting activities
- Identifying the incidence of counterfeit activity, the most at-risk channels and activities, and participants involved in these illegal activities
- Gaining wide buy-in of all participants
- Implementing appropriate regulatory authority to drive the changes
- Consistent nationwide regulations instead of a patchwork of local legislation in order to assure the uninterrupted flow of vital drugs within an interstate commerce model
- Nationwide regulations for licensure of supply chain participants and enforcement of those regulations, including harsh penalties and clear definition of which regulatory authorities are charged with enforcement
- Timelines for implementation, using phases to address the most-urgent priorities first then tackling additional risks at later stages

We hope that the Task Force will take the following recommendations into consideration as they prepare to publish their updated report in May 2006.

Highest-Priority Recommendations:

The following recommendations are offered as a means to further secure the drug distribution supply chain in an effective, efficient, and timely manner. The following recommendations should be completed first, then the status of the counterfeit drug problem should be re-assessed and additional actions, if any, scheduled at that time. This approach allows for rapid, phased deployment of high-impact solutions that can quickly send a message that these illegal activities will not be tolerated.

It is not clear that limited resources should be applied to unproven, speculative initiatives that are technologically immature, such as RFID and e-pedigree schemes, as opposed to proven regulatory activities such as increased vigilance of traditionally under-regulated distribution pathways. Industries with more significant counterfeiting incidence, such as software and entertainment media, have benefited greatly from additional controls such as product authentication countermeasures and increased prosecution of offenders. One need only look to the recent Napster example for guidance on how to shut-down an entire illegal pathway without implementation of technology solutions.

- The Normal Chain of Distribution (NCOD) is currently highly regulated, highly effective, has relatively short and controlled supply chains, and poses little threat of counterfeit drug entry and/or proliferation. We recommend that actions to further regulate and control the NCOD be deferred and the focus be shifted to tightening less-secure distribution routes, especially the secondary wholesale market, internet pharmacies that are not licensed by the States, and off-shore pharmacies that are not licensed by the States.
- Federal legislation mandating uniform licensure and accreditation of all drug wholesalers should be initiated. The current patchwork of individual state's licensure allows different standards for each state, presents much complexity to all participants, and hinders the flow of interstate commerce. Current accreditation schemes such as VIPS and VAWD provide strong controls to ensure the legitimacy of distributors and pharmacies and provide powerful and relatively low-cost assurances of control.
- Documented Agency studies are need to clearly demonstrate, via real-world tests and pilots, that current assumptions of RFID, e-pedigree, trace/track and other related initiatives actually deliver the promised benefits and quantification of the cost/benefit to industry, and society as a whole, of pursuing these initiatives. There is insufficient documented evidence that any of these immature technologies will actually decrease counterfeiting, decrease medical errors, or otherwise improve patient safety. There should be hard data and facts weighing the need for these advanced technologies vs. 'lower-tech' solutions such as those listed in this 'Higher Priority Recommendations' section.
- Expansion of funding is needed for the FDA Office of Criminal Investigation combined with additional resources to gather intelligence and data on the incidence of counterfeiting, the pathways whereby counterfeit drugs enter the supply chain, and additional investigators and prosecutors to prosecute those participating in illegal activities. There is little data available on the sources of counterfeit drugs or the incidence of these activities, making it difficult to ensure that limited resources are deployed towards the most effective solutions.

- Federal regulations are needed requiring that a minimum set of anti-counterfeiting countermeasures be applied to all drug products. It is relatively quick and inexpensive to apply layers of security to drug products and these measures would assure participants that the drugs they handle are genuine. This is a high-impact, low-cost solution that can be rapidly deployed. These requirements should be phased-in on high-priority drug products first, then extended over time to eventually cover all drugs. A national database of drugs most likely to be counterfeited should be maintained by FDA OCI. Generic drugs, which account for 55% of written prescriptions according to the testimony at the FDA Workshop, must be included in any regulatory initiatives in order to achieve the goal.
- Implementation of harsh penalties for drug counterfeiting must be instituted. Even recent State legislation does not provide significant penalties. Harsher penalties should include mandatory sentencing and fine guidelines, seizures of assets used in the furtherance of illegal activities, confiscation and destruction of counterfeit drugs, and should provide the regulatory framework for enhanced surveillance and prosecution.
- Federal regulations regarding Internet pharmacies and importation should be promulgated. The perception within the industry is that these pathways present the greatest risks of allowing counterfeit drugs to enter the legitimate supply chains and proliferate throughout the supply chain.
- Federal requirements for product returns should be clarified. This represents a significant risk of counterfeit drugs re-entering the supply chain and essentially becoming 'laundered'.
- FDA should continue the stay on implementation of the PDMA Pedigree requirements until completion of these recommendations, re-assessment of the efficacy of these controls in combating counterfeit drugs, completion of the documented studies of more advanced controls, and the state of technology to implement more advanced controls.
- For all of the above-listed Recommendations, the Agency should set firm dates for compliance.

Lower-Priority Recommendations:

The following recommendations should only be pursued after full implementation of the Highest-Priority Recommendations listed above, and following a re-assessment of the efficacy of those controls in combating the spread of counterfeit drugs.

- Federal legislation or rulemaking is needed that that precisely defines the data content, data definitions, format, structure, and exchange of e-pedigrees between supply chain participants. Current State regulations have conflicting data requirements and definitions and continue to be a hindrance to wide-spread adoption.
- Federal legislation is needed regarding use of NDC in RFID. There must be one consistent method for identifying products using RFID.
- Federal legislation regarding frequencies for Case, Pallet, Item Level is needed. There is no consensus on the item-level frequency at present, with some advocating 13.56MHz, and some advocating 900MHz. Additionally, the 900MHz range must be globally standardized since most pharmaceutical manufacturers have multi-national distribution channels and differing frequencies will result in a proliferation of product SKU's, increased costs to consumers, and continued barriers to industry adoption.
- Federal legislation, created in cooperation with the FTC, is needed to address Privacy concerns. There must be one common solution that satisfies all of the various interests and balances the need for privacy and protection of personal information vs. the need to efficiently transact business.
- Any use of RFID must consider that the immense infrastructure needed for all trading partners to transact only EPC's and Serial Number by looking-up associated data in one or more databases (that do not yet exist) will not be available for many years. Recommend that additional data elements, such as Lot, Expiry, product Serial Number, Quantity, and other approved GS1 Application Identifiers be used as a bridge to communicate this data until such time that interoperable databases are available. Many manufacturers and distributors use GS1-compliant barcodes transacting this data, and removal of this data stream from RFID is a giant step backwards. One only need look at the current GS1 GDSN Data Pool initiatives to see the complexity and long timelines that will be required to build any kind of transactional database system with many external participants.
- There is a need to balance future requirements for advanced solutions such as Trace/Track, e-Pedigree, RFID, and other initiatives with the immense costs and long timelines to implement these technologies.

For example, for one mid-sized pharmaceutical manufacturer to tag at the item-level, the annual costs would be approximately as follows:
100 million units to tag @ $0.13/tag = $13 million per year in item-level tag costs
+ an additional 2.5 million tags for Case and Pallet level @ $0.13/tag = $325,000
Total cost for tags alone: $13.3 million per year
even at the $0.05 'holy grail' of tag costs, this results in $5.125 million per year

Question for the Agency: Is this level of spending justified, considering that no studies or assessments have been completed to quantify the impact of item-level trace/track on securing the supply chain?

- The Agency should not support the use of Serialized Barcodes in place of RFID. If the Agency wishes to achieve a future state of RFID, then implementation of serialized barcodes will be a huge distraction to the industry and will only serve to further delay any wide adoption of RFID.
  Phased-in implementations of RFID, e-pedigree, and trace/track, if warranted, should then be pursued. The best practices of Wal-Mart, Target, DoD and other key players who are successful in their implementations should be followed in regards to phasing. Start with Case and Pallet for some limited set of drugs, then moving on to additional drugs at Case and Pallet levels, then eventually assessing the cost/benefit of item-level tagging. The Agency should be realistic in its expectations for how long this phasing is likely to take. Once started, it will be many years to accomplish Case and Pallet tagging for all drugs, then many more years to achieve item-level tagging.
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Respectfully submitted,

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