



December 7, 2006

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

Re: Docket Number 2006N-0335

Dear Sir or Madam:

Provided herewith are comments submitted to FDA by Alcon Laboratories, Inc., regarding the Direct Final Rule entitled "Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data".

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](mailto:garry.heidel@alconlabs.com).

Sincerely:

A handwritten signature in cursive script that reads "Garry G. Heidel".

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

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**INTRODUCTION:**

Alcon welcomes the opportunity to comment on the Direct Final Rule entitled: "Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data" Docket Number 2006N-0335. Our intent in providing these comments is to provide the Agency with feedback regarding our interpretation and concerns with the wording and contents of the Direct Final Rule.

**GENERAL COMMENTS:**

1. A FDA Guidance is needed to describe the Agency's current thinking regarding the Quality System requirements for Reprocessing of Single-Use Devices including Good Manufacturing Practices to supplement any formal regulation or rule governing SUD reprocessors.
2. Reprocessed SUDs present additional hazards and risks to the reprocessors, users and patients that are not typical of the original SUD. Many SUDs contain materials that can be damaged or that can deteriorate during reprocessing, cleaning and sterilization. Reprocessors should be required to conduct documented Risk Assessments that address these hazards and risks.
3. Many SUDs such as needles, cannulas, and instrument tips are designed to function properly in single-use situations only. These delicate SUDs may become damaged, bent, occluded or misaligned during or after use. If the reprocessor does not have access to the original specifications for the SUD, a reprocessed SUD may not perform adequately or as expected in subsequent post reprocessing use.
4. Some used SUDs if not cleaned properly by the reprocessor can be a source of TSE or viruses such as HIV, Herpes or Hepatitis B & C. These hazards are not addresses in the Direct Final Rule.
5. Some used SUDs such as delicate surgical handpieces cannot be adequately tested or inspected to ensure that all extraneous material has been removed during cleaning, reprocessing and sterilization without destructive disassembly. Such SUDs should be specifically identified in the Direct Final Rule as "not to be reprocessed".

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6. Neither the Supplemental Information nor the Direct Final Rule includes biocompatibility requirements and testing for reprocessed SUDs. Cleaning of SUDs could result in the contamination of the SUD with solvents, cleaning agents, environmental contaminants, reprocessing materials, lubricants, oils, etc. SUDs that are difficult to clean may require the use of solvents, detergents or other cleaning agents to effectively remove tissue, debris, surgical aids, blood, and other materials. This is a critical concern with Ophthalmic surgical Single-Use Devices since cleaning residues left behind after reprocessing can result in increased incidence of inflammation, infection, allergic reactions and other adverse conditions related to contamination on or in the SUD.

**SPECIFIC COMMENTS:**

7. It is unclear in the Direct Final Rule how the “functional performance data” of a reprocessed SUD defined in 807.3(v) can be assessed or evaluated when the functional performance of the SUD entering the reprocessing steps may be unknown to the reprocessor.
8. The Direct Final Rule is silent regarding documentation requirements for procedures and data on the functional performance testing of reprocessed SUDs.
9. The Direct Final Rule does not clearly discuss if it is necessary for the reprocessed SUD to be restored to the same performance functionality as the original SUD.
10. The Direct Final Rule is unclear in describing the requirements for reprocessing of SUDs regardless of the SUD’s performance during the previous usage. It is unclear if the reprocessing should return the SUD to its original acceptable for use state or some other standard of performance.
11. The Direct Final Rule is unclear regarding refurbishing SUDs that may involve removal of parts or material from the SUD and or replacement of certain parts or materials of the SUD.
12. There is no requirement in the Direct Final Rule that the reprocessor defines or determines the minimum acceptable specifications for the SUD when it comes back from surgery to insure that only the SUDs meeting these minimum specifications will be formally approved for reprocessing.

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13. The Direct Final Rule does not include a requirement to determine and define specific criteria for the reprocessed SUD that expands beyond functional performance data. This step would ensure that a reprocessed SUD is equivalent to the original SUD and is safe and effective for use in a subsequent surgery or procedure.
14. The Direct Final Rule does not include requirements for documented incoming inspection procedures and criteria for used SUDs to insure that the validated reprocessing steps will result in a safe and effective reprocessed SUD.
15. The Direct Final Rule does not include requirements for assessing the physical and mechanical condition of used SUDs received for reprocessing. If the reprocessor does not evaluate the physical and mechanical condition of the incoming used SUD for defects such as dents, damage, deterioration, scratches, cracks, occlusions, etc. and considers only the cleaning and sterilization in the reprocessing activities, the reprocessed SUD may not perform in an equally effective manner as the original SUD. The reprocessor must consider the physical and mechanical condition of the used SUD as a critical step in the evaluation process prior to initiating reprocessing steps.
16. The Direct Final Rule should include a mechanism/requirement for documenting the traceability of each reprocessed SUD so that reprocessor assumes responsibility and liability for reporting any adverse events, injuries or other failures resulting from the use of the reprocessed SUD. Without this traceability, the original manufacturer of the SUD can be inappropriately held responsible for issues and problems associated with the reprocessed SUDs.
17. Section 807.3 Definitions does not include a definition for “functional performance data”. The standard(s) for assessing functional performance is not addressed in the Direct Final Rule.
18. Section 807.3 Definitions: The definition of “validation data” is ambiguous and does not provide the level of detail necessary to ensure that appropriate validation activities and documentation are performed by the reprocessor of SUDs. Process validation requirements should be defined for performance testing, cleaning and sterilization processes required by the Direct Final Rule.

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19. Section 807.3(v), the term “substantially equivalent” is not defined and is ambiguous. The term should be defined such that it is understood that the reprocessed SUD is biocompatible, functional, effective and safe for its intended use.

*END*