Roberta L McKee, Ph D
Vice President
Vaccine & Sterile Quality Operations

Merck & Co , Inc
WP36M-5
P O Box 4
770 Sumneytown Pike
West Point PA 19486-0004
E-mail roberta_mckee@merck com
Tel 215 652 5603
Fax 215 993 3400

MERCK
Manufacturing Division

VIA FEDERAL EXPRESS

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

RE: Comment to Docket 01D-0221
Draft Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components

Given that FDA has formally launched a "Risk Based Approach" to GMPs as communicated at the FDA/PQRI Workshop on a Drug Quality System in the 21st Century conducted in Washington, D.C. April 22-24, 2003, we respectfully request that the Draft Guidance for Industry Docket 01D-0221 be re-evaluated and amended to include principles for BPDR reporting in alignment with FDA's Risk Based Approach. For example, for the following Draft Guidance Excerpt:

> "*If you discover a deviation or unexpected event **after** distribution of any affected products and the safety, purity, or potency of the product may have been affected at the time of distribution, you are required to report the event. You must report the event under 21 CFR 606.171 even if you determine, through investigation, that the safety, purity or potency of the product was not affected. For example, if you distributed an untested unit, you must report that to FDA, even if you subsequently tested the unit and found it to be negative.*"

While Merck & Co., Inc. acknowledges CBER's intent to monitor post-marketing deviations to provide useful insight into deviations within industry, we question the requirement to file a BPDR in cases where definitive scientific evidence exists that supports product quality. For example, we question the need for filing a BDPR when satisfactory test results for an untested unit or a missed stability test within a stability time frame are available within the 45-day filing

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timeframe. We agree that an investigation would be required at the manufacturer where the deviation occurred and that the event must be fully recorded, evaluated and investigated in accordance with 21 CFR 211.192 and 211.198 for drug product quality impact. We question the value of reporting this information when clear scientific information is available to support product quality. We find the reporting of events where it can be determined at the time of filing that there was no quality impact due to satisfactory data is counter to the "Risk Based Approach" currently being implemented by FDA. We feel the guidance should be amended and clarified to include the requirements and expectations on reporting of untested units to reflect this position as well as amended more generally to effectuate a "Risk Based Approach".

Sincerely,

Roberta L. McKee

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