07 September 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Rm. 1061
Rockville, MD 20852

Re: Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-threatening Diseases: Implementation Plan
Docket No. 00D-1033, Federal Register Vol. 66 (09 July 2001)

Dear Sir or Madam,

Biomira appreciates the opportunity to comment on FDA's Draft Guidance for Industry entitled "Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan" published in the 09 July 2001 issue of the Federal Register. The comments provided address a number of questions and concerns with respect to FDA's implementation plan for the Clinical Trials Data Bank as described by this guidance and the previously released Draft Guidance for Industry entitled "Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank". Biomira respectfully requests FDA's consideration of the following points with respect to its implementation and administration of the Clinical Trials Data Bank.

1. It is our interpretation that this statute is meant to apply to clinical studies of drugs intended to treat a serious or life-threatening disease conducted under FDA's IND regulations (21 CFR Part 312). It would be helpful to clarify if clinical trials conducted under a US IND but without US clinical trial sites are required to be listed in the Clinical Trials Data Bank. Furthermore, it would be helpful to clarify if foreign trial sites are required to be listed.

2. For clinical trials in progress, it would be helpful to specify if trials or trial sites already closed to enrollment are required to be listed in the Clinical Trials Data Bank.

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3. Section 113 of FDAMA also applies to "group C protocols". It would be helpful to define this term in the final draft guidance.

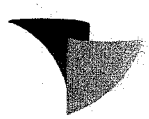
4 Additional guidance is requested to define reasonable timeframes for updates to the data bank. In a letter of comment (dated 30 May 2000) to the draft guidance on the establishment of a data bank, the Pharmaceutical Research and Manufacturers of America suggested the grouping and submission of updates at 30-day intervals, as is allowed for information updates regarding investigators under 21 CFR 312.30(e). The allowance of reasonable timeframes for information updates should be considered.

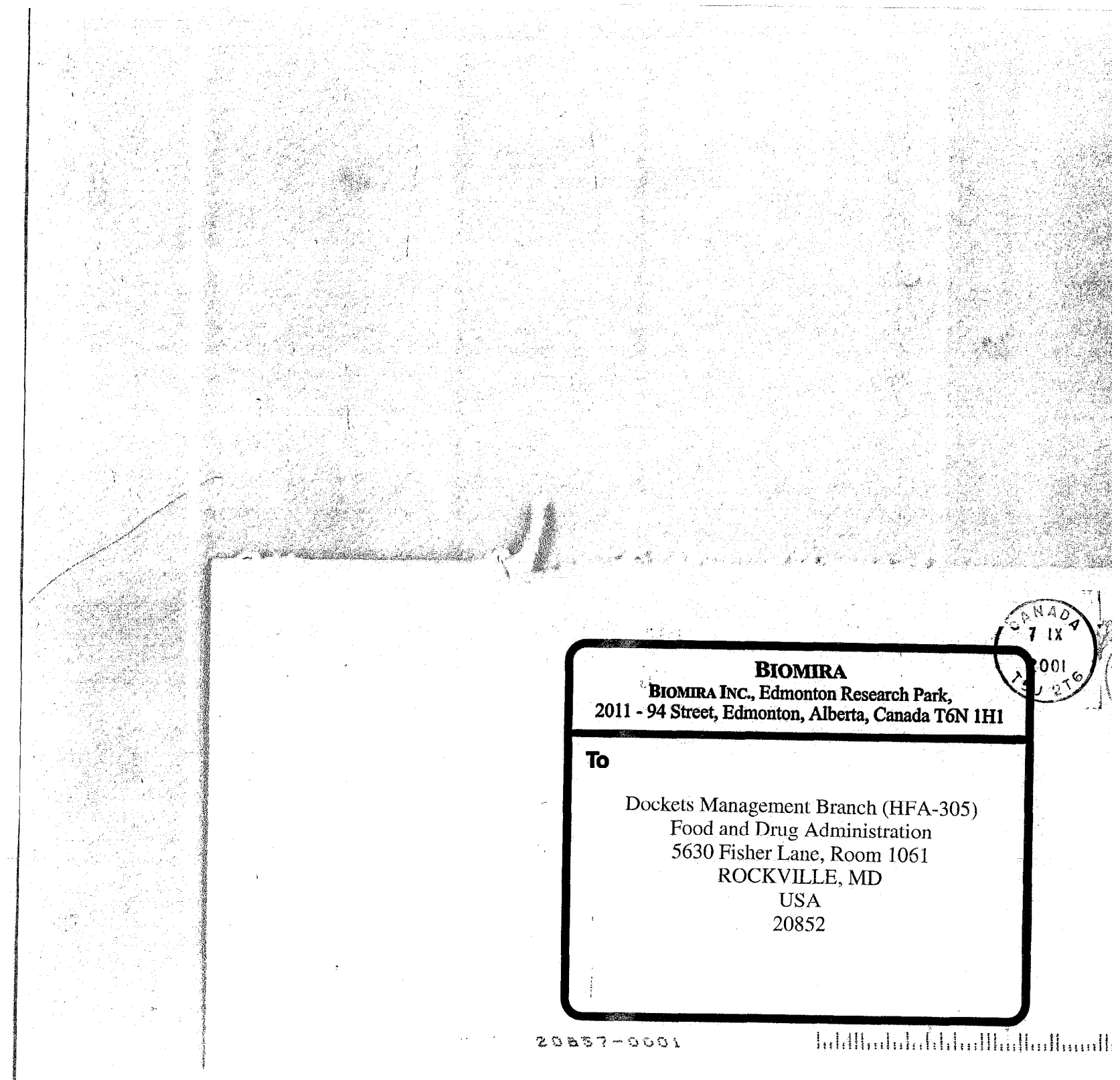
5. It was indicated in the draft guidance regarding the establishment of the data bank that prior Institutional Review Board (IRB) approval would not be required for submitting information to the Clinical Trials Data Bank. It has been our experience that IRB approval is required whenever disclosing trial information for a specific institution (e.g. names of investigators, site contacts, etc.). Clarification on this point would be helpful.

We hope the above comments are helpful to FDA in its efforts to finalise its Clinical Trials Data Bank guidance. If you have any questions or should you require further clarifications regarding any of the points raised in Biomira's comments, please do not hesitate to contact me at (780) 490-2809 or by facsimile at (780) 463-0871.

Sincerely,
BIOMIRA Inc.

Marilyn Olson
Director, Regulatory Affairs





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