

**MEMORANDUM OF UNDERSTANDING
BETWEEN
THE FOOD AND DRUG ADMINISTRATION
AND
THE NATIONAL TREASURY EMPLOYEES UNION**

This memorandum records the agreements concluded by the above parties related to implementation of the Office of Regulatory Affairs' (ORA) Turbo Establishment Inspection Reporting (EIR) System. The parties agree that the FDA has now satisfied its collective bargaining obligations related to this matter and is free to proceed with implementation of the system consistent with the provisions of this memorandum.

- 1) The Center for Devices and Radiological Health does not anticipate that the implementation of Turbo EIR will have any adverse impact upon any of the FDA Center employees who currently perform form 483 analysis and review; Further, the management will make all reasonable efforts to avoid any adverse impact flowing from Turbo EIR implementation. In the unlikely event that there should be a need to reduce positions or grades as a result of implementation of Turbo EIR, the FDA acknowledges its obligation, pursuant to the law and Article 3 of the Collective Bargaining Agreement, to notify NTEU and negotiate, upon request, the implementation and impact of those reductions.
- 2) ORA agrees that it is not its intent to require increased productivity as a result of the implementation of Turbo EIR. More specifically, ORA does not intend to require employees to decrease the amount of time spent on inspections and/or inspectional reporting due to their use of Turbo EIR. Furthermore in preparing performance evaluations, ORA will make appropriate allowances for any decrease in productivity that might be experienced by employees being trained and learning to use Turbo EIR.
- 3) ORA employees will receive a reasonable amount of training in Turbo EIR prior to being required to utilize the program. Employees who experience difficulty in running the program will be offered retraining.
- 4) All ORA employees required to use Turbo EIR (other than at their desktop computers) will be provided with appropriate carry bags for the laptop, printer, and other supporting equipment that it will be necessary for them to carry.
- 5) All ORA employees required to use Turbo EIR overseas will be provided with appropriate electric power adapters or converters.
- 6) At their request, pursuant to Article 7 of the FDA/NTEU Collective Bargaining Agreement, NTEU will be provided with a copy of a report or reviews of the Turbo EIR program issued after its initial implementation is completed. Any report or review of the

TURBO EIR program furnished the Union will be redacted for information which ORA may not release publicly, e.g., trade secrets, confidential commercial, informant, and deliberative process information. Furthermore, pursuant to law and Article 3 of the FDA/NTEU Collective Bargaining Agreement, NTEU will be provided with an opportunity to negotiate any significant changes to the Turbo EIR program which are proposed in the future and which affect conditions of employment.

For the NTEU:

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For the FDA:

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