

March 11, 1999

0088
Dr. Mahmoud A. ElSohly
ElSohly Laboratories, Inc.
5 Industrial Park Drive
Oxford, MS 38655

Dear Dr. ElSohly:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the seventeenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable.

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is not necessary for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson NLCP Inspection Analyst

Deborah Allenson

Enclosure

cc: Project Files/17



## NATIONAL LABORATORY CERTIFICATION PROGRAM

# **Document Review and Critique** Laboratory I.D. Number: 0088 Document No. Final Laboratory: ElSohly Laboratories, Inc. Location: Oxford, MS ] Application Form **Document Reviewed:** [XX] Inspection Report #M17 Date: 11 February 1999 [ ] Other \_\_\_\_\_ Status: [XX] Highly Acceptable ] Acceptable [ ] Unacceptable ] Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance



September 30, 1999

0088
Dr. Mahmoud A. ElSohly
ElSohly Laboratories, Inc.
5 Industrial Park Drive
Oxford, MS 38655

Dear Dr. ElSohly:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the eighteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable.

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson NLCP Inspection Analyst

Deborah J. De

Enclosure

cc: Project Files/M18



### NATIONAL LABORATORY CERTIFICATION PROGRAM

# **Document Review and Critique**

Laboratory I.D. Number: 0088

Document No. Final

Laboratory: <u>ElSohly Laboratories, Inc.</u>

Location: Oxford, MS

Document Reviewed: [ ] Application Form

[XX] Inspection Report #M18 Date: 26 August 1999

Status: [XX] Highly Acceptable [ ] Acceptable [ ] Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

Ver. Final Lab ID# 0088

The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

Ver. Final Lab iD# 0088

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance



March 3, 2000

0088
Dr. Mahmoud A. ElSohly
ElSohly Laboratories, Inc.
5 Industrial Park Drive
Oxford, MS 38655

Dear Dr. ElSohly:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the nineteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.

- E. The Standard Operating Procedures (SOP) section
- F. The Chain of Custody, Accessioning, and Security section acceptable. However, the following issue was raised:

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.



Dr. ElSohly March 3, 2000 Page 2 of 2

If you have any questions or if we can be of further assistance, please call me at  $(919)\ 541-7265$  or Dr. Michael Baylor at  $(919)\ 541-7043$ .

Sincerely,

Deborah J. Denson NLCP Inspection-Analyst

**Enclosure** 

cc: Project Files/M19

# NATIONAL LABORATORY CERTIFICATION PROGRAM

### **Document Review and Critique** Laboratory I.D. Number: 0088 Document No. Final ElSohly Laboratories, Inc. Laboratory: Location: Oxford, MS Document Reviewed: [ ] Application Form [XX] Inspection Report #M19 Date: 10 February 2000 [ ] Other \_\_\_\_ [XX] Highly Acceptable Status: ] Acceptable ] Unacceptable ] Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

Ver. Final

Lab ID# 0088

The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

Ver, Final Lab ID# 0088

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance





October 10, 2000

0088 .
Dr. Mahmoud A. ElSohly
ElSohly Laboratories, Inc.
5 Industrial Park Drive
Oxford, MS 38655

Dear Dr. ElSohly:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twentieth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable.

RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. It is *not necessary* for the laboratory to submit a written response to RTI. All corrective actions will be reviewed during the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson NLCP Technical Analyst

Deborah & De

Enclosure

cc: Project Files/M20



# NATIONAL LABORATORY CERTIFICATION PROGRAM Document Review and Critique Laboratory I.D. Number: 0088 Document No. Final Laboratory: ElSohly Laboratories, Inc. Location: Oxford, MS Document Reviewed: [ ] Application Form [XX] Inspection Report #M20 [ ] Other \_\_\_\_\_\_ Date: 24 August 2000

1 Acceptable

] Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

[XX] Highly Acceptable

[ ] Unacceptable

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

Status:

Ver. Final Lab ID# 0088

The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance