[21 CFR Part 1305]

ANONYMOUS TESTING BY LABORATORIES

Proposed Modification of Order Form Requirements

Section 308 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 828) establishes a system of order forms for controlled substances in Schedules I and II and provides that the Attorney General shall prescribe regulations pursuant to the section. The regulations in Title 21 of the Code of Federal Regulations, Part 1305, implement the order form system and in § 1305.03 provide various exceptions to the order form requirements.

Many registered analytical laboratories in the United States are accepting small quantities of controlled substances from anonymous sources for the purpose of analyzing the drug sample. A survey of various laboratories engaged in such anonymous testing of "street samples" revealed that the practices and security of the programs varied widely. Therefore, standardized guidelines have been prepared, and it is proposed that a specific exception to the existing order form requirements be promulgated based on a written waiver issued by the Regional Director in the Region in which the laboratory involved is located. The waiver would be granted upon the agreement of the laboratory to conduct its activities in accordance with guidelines established by the Administration.

It is proposed that the following guidelines would be utilized to provide reasonable controls over activities of the laboratories that are accepting controlled substances from anonymous sources for purposes of analysis:

GUIDELINES FOR ANALYTICAL LABORATORIES DESIRING TO CONDUCT ANALYSIS OF ANONYMOUS SAMPLES

DEA Policy. Currently there are a number of advocates of these laboratories among law enforcement, the pharmaceutical industry, medical authorities, the rehabilitation and treatment community, and the general public. Correspondingly, there are a number of adversaries. DEA will allow the operation of these laboratories under the guidelines set forth below until such time that it can be determined whether the purported benefits outweigh the adverse effects or vice versa. These guidelines establish a uniform policy regarding the operation and registration of these laboratories.

(A) *Registration.* Each physical location at which drugs are collected or analyzed must be registered. As an analytical laboratory, Federal registration must be for all five schedules and the firm must be approved by the State to conduct such activities (see also section I).

(B) *Method of submission.* Delivery of samples to lock boxes at locations which are not registered, or specifically exempted, will not be permitted. Possession of controlled substances by non-registrants will be subject to all legal provisions of CSA.

(C) *Type of analysis done.* Quantitative analysis may be conducted. However, to prevent the possibility of dealers utilizing these laboratories as a quality control, only qualitative results may be given to the donor. Analysis should be sufficient to determine if dangerous adulterants are in the sample or if the strength is so great that use would be harmful to the user. In these cases, the submitter can only be told what the drug was and that use would be dangerous.

(D) *Recordkeeping.* Each person registered as an analytical laboratory and engaged in the receipt and analysis of anonymous samples shall maintain records containing the following information (to the extent known and reasonably ascertainable by him):

(1) Laboratory identification number.
(2) Date sample received.
(3) Purported contents and actual identification.
(4) Quantity received.
(5) Form of sample (i.e., powder, liquid, tablet, etc.).
(6) Description of sample.
(7) Quantity utilized in analysis.
(8) Disposition of sample.
(9) Street price, if known.
(10) Method shipment received.

(E) *Security.* Physical security should be the same as that for a practitioner with the exception that all samples must be treated as Schedules I and II. These requirements are outlined in §§ 1301.75 and 1301.76 of 21 CFR. Copies are available at the DEA Regional Office.

(F) *Qualifications of persons operating the laboratory.* The individuals conducting these programs must have the appropriate chemical background to enable proper analysis of the substances involved. One person involved in the program must have the minimum of a college degree in chemistry or a closely related field. Adequate equipment suitable for conducting such analysis must be possessed by the laboratory.

(G) *Disposition of samples.* In accordance with current regulations, contact the Regional DEA Office prior to disposition of any samples.

(H) *Periodic reports to DEA.* Each laboratory should submit to the DEA Regional Director a quarterly report containing at least the following information:

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(1) Actual content of drug analyzed.
(2) Alleged content of drug analyzed.
(3) Description of sample.
(4) Origin of sample.
(5) Street price, if known.

(I) *Order Form Requirements.* Each analytical laboratory desiring to conduct anonymous sampling must apply to the DEA Regional Director for a written waiver of the order form requirement. The DEA Regional Director will issue in writing a waiver of this requirement if all qualifications under CSA are met. This written waiver shall include the statement that the waiver is issued with the provision that the laboratory will conduct its activities in accordance with the above guidelines and that any deviation therefrom will result in withdrawal of the waiver. A copy of the Guidelines will be attached to the written waiver. Withdrawal of the waiver will be in the form of written correspondence from the Regional Director. Once this withdrawal is issued, the laboratory must cease all anonymous analytical work.

Therefore, under the authority vested in the Attorney General by section 308 (a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 828(a)), delegated to the Administrator of the Drug Enforcement Administrator of the Drug Enforcement Administration by 28 CFR 0.100, and to the Deputy Administrator by Directive 73-2, 38 FR 34662, December 17, 1973, it is proposed that a new paragraph (f) be added to § 1305.03 of Title 21 of the Code of Federal Regulations as follows:

§ 1305.03 Distributions requiring order forms.

An order form (BND Form 222c) is required for each distribution of a controlled substance listed in schedule I or II, except for the following:

§ 1305.03 Distributions requiring order forms.

An order form (BND Form 222c) is required for each distribution of a controlled substance listed in schedule I or II, except for the following:

* * * * *

(f) The delivery of such substances to a registered analytical laboratory, or its agent approved by DEA, from an anonymous source for the analysis of the drug sample: *Provided,* The laboratory has obtained a written waiver of the order form requirement from the Regional Director of the Region in which the laboratory is located, which waiver may be granted upon agreement of the laboratory to conduct its activities in accordance with Administration guidelines.

All interested persons are invited to submit their comments and objections in writing regarding this proposal. Comments and objections should be submitted in quintuplicate to the Office of Chief Counsel, Drug Enforcement Administration, Department of Justice, Room 611, 1405 I Street NW., Washington, D.C. 20537, and must be received on or before April 1, 1974.

Dated: February 25, 1974.

ANDREW C. TARTAGLINO,
Acting Deputy Administrator,
Drug Enforcement Administration.

[FR Doc.74-4765 Filed 2-27-74;8:45 am]

[21 CFR Part 1305]
[1974 February 28 – Federal Register Volume 39, Number 41]
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Many registered analytical laboratories in the United States are accepting small quantities of controlled substances from anonymous sources for the purpose of analyzing the drug sample. A survey of various laboratories engaged in such anonymous testing of "street samples" revealed that the practices and security of the programs varied widely. Therefore, standardized guidelines have been prepared, and it is proposed that a specific exception to the existing order form requirements be promulgated based on a written waiver issued by the Regional Director in the Region in which the laboratory involved is located. The waiver would be granted upon the agreement of the laboratory to conduct its activities in accordance with guidelines established by the Administration.

It is proposed that the following guidelines would be utilized to provide reasonable controls over activities of the laboratories that are accepting controlled substances from anonymous sources for purposes of analysis:

Guidelines for Analytical Laboratories Desiring to Conduct Analysis of Anonymous Samples

DEA Policy. Currently there are a number of advocates of these laboratories among law enforcement, the pharmaceutical industry, medical authorities, the rehabilitation and treatment community, and the general public. Correspondingly, there are a number of adversaries. DEA will allow the operation of these laboratories under the guidelines set forth below until such time that it can be determined whether the purported benefits outweigh the adverse effects or vice versa. These guidelines establish a uniform policy regarding the operation and registration of these laboratories.

(A) Registration. Each physical location at which drugs are collected or analyzed must be registered. As ah analytical laboratory, Federal registration must be for all five schedules and the firm must be approved by the State to conduct such activities (see also section I).

(B) Method of submission. Delivery of samples to lock boxes at locations which are not registered, or specifically exempted, will not be permitted. Possession of controlled substances by non-registrants will be subject to all legal provisions of CSA.

(C) Type of analysis done, Quantitative analysis may be conducted. However, to prevent the possibility of dealers utilizing these laboratories as a quality control, only qualitative results may be given to the donor. Analysis should be sufficient to determine if dangerous adulterants are in the sample or if the strength is so great that use would be harmful to the user. In these cases, the submitter can only be told what the drug was and that use would be dangerous.

(D) Recordkeeping. Each person registered as an analytical laboratory and engaged in the receipt and analysis of anonymous samples shall maintain records containing the following information (to the extent known and reasonably ascertainable by him) :

(1) Laboratory identification number.
(2) Date sample received.
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(E) Security. Physical security should be the same as that for a practitioner with the exception that all samples must be treated as Schedules I and II. These requirements are outlined in §§ 1301.75 and 1301.76 of 21 CFR. Copies are available at the DEA Regional Office.

(F) *Qualifications of persons operating the laboratory.* The individuals conducting these programs must have the appropriate chemical background to enable proper analysis of the substances involved. One person involved in the program must have thé minimum of a college degree in chemistry or a closely related field. Adequate equipment suitable for conducting such analysis must be possessed by the laboratory.

(G) Disposition of samples. In accordance with current regulations, contact the Regional DEA Office prior to disposition of any samples.

(H) Periodic reports to DEA. Each laboratory should submit to the DEA Regional Director a quarterly report containing at least the following information;

(1) Actual content of drug analyzed.
(2) Alleged content of drug analyzed.
(3) Description of sample.
(4) Origin of sample.
(5) Street price, if known.

(I) Order Form Requirements. Each analytical laboratory desiring to conduct anonymous sampling must apply to the DEA Regional Director for a written waiver of the order form

requirement. The DEA Regional Director will issue in writing a waiver of this requirement if all qualifications under CSA are met. This written waiver shall include the statement that the waiver is issued with the provision that the laboratory will conduct its activities in accordance with the above guidelines and that any deviation therefrom will result in withdrawal of the waiver. A copy of the Guidelines will be attached to the written waiver. Withdrawal of the waiver will be in the form of written correspondence from the Regional Director. Once this withdrawal is issued, the laboratory must cease all anonymous analytical work.

Therefore, under the authority vested in the Attorney General by section 308 (a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 828(a)), delegated to the Administrator of the Drug Enforcement Administration by 28 CFR 0.100, and to the Deputy Administrator by Directive 73-2, 38 FR 34662, December 17, 1973, it is proposed that a new paragraph (f) be added to § 1305.03 of Title 21 of the Code of Federal Regulations as follows:

§ 1305.03 **Distributions requiring order forms.**

An order form (BND Form 222c) is required for each distribution of a controlled substance listed in schedule I or II, except for the following:

* * * * *

(f) The delivery of such substances to a registered analytical laboratory, or its agent approved by DEA, from an anonymous source for the analysis of the drug sample: *Provided*, The laboratory has obtained a written waiver of the order form requirement from the Regional Director of the Region in which the laboratory is located, which waiver may be granted upon agreement of the laboratory to conduct its activities in accordance with Administration guidelines.

All interested persons are invited to submit their comments and objections in writing regarding this proposal. Comments and objections should be submitted in quintuplicate to the Office of Chief Counsel, Drug Enforcement Administration, Department of Justice, Room 611, 1405 I Street NW., Washington, D.C. 20537, and must be received on or before April 1,1974.

Dated: February 25,1974.

Andrew C. Tartaglino,
Acting Deputy Administrator,
Drug Enforcement Administration.

[FR Doc.74-4765 Filed 2-27-74; 8:45 am]

federal register

Area Code 202 Phone 523-5240

Title 21—Food and Drugs

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1305—ORDER FORMS

Anonymous Testing by Laboratories

On February 28, 1974, the Drug Enforcement Administration published in the FEDERAL REGISTER (39 FR 7800) a proposal to amend 21 CFR 1305.03 to allow a waiver of order form requirements for analytical laboratories which analyze anonymous drug samples.

No objections were received regarding the proposed regulation, but one comment was received from Mr. Kenneth Baumgartner, a private attorney, that he believed that the guidelines (which were included as background information in the proposal) should be published as part of the regulation. However, since the guidelines were included in the proposal, and will be attached to the written waiver granted under the regulation, it is not deemed necessary to publish the guidelines as a part of the final regulation.

Therefore, under the authority vested in the Attorney General by section 308(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 [21 U.S.C. 828(a)], delegated to the Administrator of the Drug Enforcement Administration by 28 CFR 0.100, and to the Deputy Administrator by Directive 73-2, 38 FR 34662, December 17, 1973, 21 CFR 1305.03 is amended by adding a new paragraph (f) as follows:

§ 1305.03 Distributions requiring order forms.

An order form (BND Form 222c) is required for each distribution of a controlled substance listed in schedule I or II, except for the following:

* * * * *

(f) The delivery of such substances to a registered analytical laboratory, or its agent approved by DEA, from an anonymous source for the analysis of the drug sample, provided the laboratory has obtained a written waiver of the order form requirement from the Regional Director of the Region in which the laboratory is located, which waiver may be granted upon agreement of the laboratory to conduct its activities in accordance with Administration guidelines.

This regulation shall become effective May 30, 1974.

Dated: April 25, 1974.

ANDREW C. TABALINO,
Acting Deputy Administrator,
Drug Enforcement Administration.

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[21 CFR Part 1305—ORDER FORMS]
[1974 April 25 – Federal Register Volume 39, Number ??]
[Extracted from DEA Microgram Journal 1974 October: Volume 7, Number 10 (by Erowid)]
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ANONYMOUS TESTING BY LABORATORIES

Final Order

Federal Register
Area Code 202 Phone 523-5240
Title 21 -- Food and Drugs
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Anonymous Testing by Laboratories

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(f) The delivery of such substances to a registered analytical laboratory, or its agent approved by DEA, from an anonymous source for the analysis of the drug sample, provided the laboratory has obtained a written waiver of the order form requirement from the Regional Director of the

Region in which the laboratory is located, which waiver may be granted upon agreement of the laboratory to conduct its activities in accordance with Administration guidelines.

This regulation shall become effective, May 30, 1974.

Dated: April 25, 1974.

ANDREW C. TARTAGLINO
Active Depute Administrator
Drug Enforcement Administration
[FR DOC. 74-9833 Filed 4-29-74;8:45 am]