

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 341 be amended as follows:

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTI-ASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 341.74 is amended by adding paragraphs (c)(5)(iii), (c)(5)(iv), and (c)(5)(v), and revising paragraphs (d)(2)(i), (d)(2)(ii), (d)(2)(iv), and (d)(2)(v) to read as follows:

§ 341.74 Labeling of antitussive drug products.

* * * * *

(c) * * *

(5) * * *

(iii) *For any product containing camphor or menthol in a suitable ointment vehicle or for steam inhalation use.*—(A) The labeling should contain an appropriate flammability signal word, e.g., “extremely flammable,” “flammable,” “combustible,” consistent with 16 CFR 1500.3(b)(10).

(B) “Keep away from fire or flame.”

(iv) *For any product formulated in a volatile vehicle.* “Cap container tightly and store at room temperature away from heat.”

(v) *For any product with labeling that contains warnings, the following information shall appear after the subheader “Do Not Use.”*—(A) “Near an open flame.”

(B) “By adding to hot water.”

(C) “In a microwave oven.”

(D) “In a container in which water is being heated, except when adding to cold water in only a hot steam vaporizer.”

(d) * * *

(2) * * *

(i) *For products containing camphor identified in § 341.14(b)(1) in a suitable ointment vehicle.* The product contains 4.7 to 5.3 percent camphor. Adults and children 2 to under 12 years of age: Rub on the throat and chest in a thick layer. Cover with a warm, dry cloth if desired. However, clothing should be loose about throat and chest to help vapors reach the nose and mouth. Use up to three times daily or as directed by a doctor. Children under 2 years of age: Consult a doctor. “See important warnings about not using near a flame, in hot water, or in a microwave oven. Improper use may cause the mixture to

splatter and cause burns.” (Last two sentences to be highlighted in bold type or contrasting color.)

(ii) *For products containing menthol identified in § 341.14(b)(2) in a suitable ointment vehicle.* The product contains 2.6 to 2.8 percent menthol. Adults and children 2 to under 12 years of age: Rub on the throat and chest in a thick layer. Cover with a warm, dry cloth if desired. However, clothing should be loose about throat and chest to help vapors reach the nose and mouth. Use up to three times daily or as directed by a doctor. Children under 2 years of age: Consult a doctor. “See important warnings about not using near a flame, in hot water, or in a microwave oven. Improper use may cause the mixture to splatter and cause burns.” (Last two sentences to be highlighted in bold type or contrasting color.)

* * * * *

(iv) *For products containing camphor identified in § 341.14(b)(1) for steam inhalation use.* The product contains 6.2 percent camphor. Adults and children 2 to under 12 years of age: Add 1 tablespoonful of solution, for each quart of water, or add 1½ teaspoonsful of solution, for each pint of water, directly to cold water in only a hot steam vaporizer. Breathe in the medicated vapors. Use up to three times daily or as directed by a doctor. Children under 2 years of age: Consult a doctor. “See important warnings about not using near a flame, in hot water, or in a microwave oven. Improper use may cause the mixture to splatter and cause burns.” (Last two sentences to be highlighted in bold type or contrasting color.)

(v) *For products containing menthol identified in § 341.14(b)(2) for steam inhalation use.* The product contains 3.2 percent menthol. Adults and children 2 to under 12 years of age: Add 1 tablespoonful of solution, for each quart of water, or add 1½ teaspoonsful of solution, for each pint of water, directly to cold water in only a hot steam vaporizer. Breathe in the medicated vapors. Use up to three times daily or as directed by a doctor. Children under 2 years of age: Consult a doctor. “See important warnings about not using near a flame, in hot water, or in a microwave oven. Improper use may cause the mixture to splatter and cause burns.” (Last two sentences to be highlighted in bold type or contrasting color.)

Dated: July 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF JUSTICE

28 CFR Part 23

[OJP (BJA)—1177]

RIN 1121–ZB14

Criminal Intelligence Sharing Systems; Policy Clarification

AGENCY: Bureau of Justice Assistance (BJA), Office of Justice Programs (OJP), Justice.

ACTION: Proposed clarification of policy.

SUMMARY: The current policy governing the entry of identifying information into criminal intelligence sharing systems requires clarification. This policy clarification is to make clear that the entry of individuals, entities and organizations, and locations that do not otherwise meet the requirements of reasonable suspicion is appropriate when it is done solely for the purposes of criminal identification or is germane to the criminal subject’s criminal activity. Further, the definition of “criminal intelligence system” is clarified. While this clarification is not a rulemaking for the purposes of the Administrative Procedure Act, 5 U.S.C. 553, BJA is of the opinion that this clarification is significant enough to warrant public comment.

DATES: Public comment is due by September 18, 1998. Comments may be faxed to (202) 307–1419, e-mailed to “fisheral@ojp.usdoj.gov,” or mailed to the Office of the General Counsel, 810 7th Street NW, Washington, DC, 20531.

FOR FURTHER INFORMATION CONTACT: Paul Kendall, General Counsel, Office of Justice Programs, 810 7th Street NW, Washington, DC 20531, (202) 307–6235.

SUPPLEMENTARY INFORMATION: The operation of criminal intelligence information systems is governed by 28 CFR Part 23. This regulation was written to both protect the privacy rights of individuals and to encourage and expedite the exchange of criminal intelligence information between and among law enforcement agencies of different jurisdictions. Frequent interpretations of the regulation, in the form of policy guidance and correspondence, have been the primary method of ensuring that advances in technology did not hamper its effectiveness.

Use of Identifying Information

28 CFR 23.3(b)(3) states that criminal intelligence information that can be put into a criminal intelligence sharing system is "information relevant to the identification of and the criminal activity engaged in by an individual who or organization which is reasonably suspected of involvement in criminal activity, and * * * [m]eets criminal intelligence system submission criteria." Further, 28 CFR 23.20(a) states that a system shall only collect information on an individual if "there is reasonable suspicion that the individual is involved in criminal conduct or activity and the information is relevant to that criminal conduct or activity." 28 CFR 23.20(b) extends that limitation to collecting information on groups and corporate entities.

In an effort to protect individuals and organizations from the possible taint of having their names in intelligence systems (as defined at 28 CFR § 23.3(b)(1)), the Office of Justice Programs has previously interpreted this section to allow information to be placed in a system only if that information independently meets the requirements of the regulation. Information that might be vital to identifying potential criminals, such as favored locations and companions, or names of family members, has been excluded from the systems. This policy has hampered the effectiveness of many criminal intelligence sharing systems.

Given the swiftly changing nature of modern technology and the expansion of the size and complexity of criminal organizations, the Bureau of Justice Assistance (BJA) has determined that it is necessary to clarify this element of 28 CFR Part 23. Many criminal intelligence databases are now employing "Comment" or "Modus Operandi" fields whose value would be greatly enhanced by the ability to store more detailed and wide-ranging identifying information. This may include names and limited data about people and organizations that are not suspected of any criminal activity or involvement, but merely aid in the identification and investigation of a criminal suspect who independently satisfies the reasonable suspicion standard.

Therefore, BJA issues the following clarification to the rules applying to the use of identifying information. Information that is relevant to the identification of a criminal suspect or to the criminal activity in which the suspect is engaged may be placed in a criminal intelligence database, provided that (1) appropriate disclaimers accompany the information noting that

is strictly identifying information, carrying no criminal connotations; (2) the identifying information may not be used as an independent basis to target a subject for investigation or to establish reasonable suspicion of involvement in criminal activity; and (3) the individual who is the criminal suspect identified by this information otherwise meets all requirements of 28 CFR Part 23. This information may be a searchable field in the intelligence system.

For example: A person reasonably suspected of being a drug dealer is known to conduct his criminal activities at the fictional "Northwest Market." An agency may wish to note this information in a criminal intelligence database, as it may be important to future identification of the suspect. Under the previous interpretation of the regulation, the entry of "Northwest Market" would not be permitted, because there was no reasonable suspicion that the "Northwest Market" was a criminal organization. Given the current clarification of the regulation, this will be permissible, provided that the information regarding the "Northwest Market" was clearly noted to be non-criminal in nature. For example, the data field that "Northwest Market" was entered in could be marked "Non-Criminal Identifying Information," or the words "Northwest Market" could be followed by a parenthetical comment such as "This organization has been entered into the system for identification purposes only—it is not suspected of any criminal activity or involvement." "Northwest Market" could not become the target of an investigation solely on the basis of the information provided in the comment field on the suspected drug dealer. Independent information would have to be obtained as a basis for the opening of an investigative file or the submission of intelligence information, based on reasonable suspicion, on "Northwest Market." Further, the fact that other individuals frequent "Northwest Market" would not provide a reasonable suspicion determination for those other individuals.

The Definition of a "Criminal Intelligence System"

The definition of a "criminal intelligence system" is given in 28 CFR 23.3(b)(1) as the "arrangements, equipment, facilities, and procedures used for the receipt, storage, interagency exchange or dissemination, and analysis of criminal intelligence information" Given the fact that cross-database searching techniques are now commonplace, and given the fact that multiple databases may be contained on the same

computer system, BJA has determined that this definition needs clarification, specifically to differentiate between criminal intelligence systems and non-intelligence systems.

The comments to the 1993 revision of 28 CFR Part 23 noted that "[t]he term 'intelligence system' is redefined to clarify the fact that historical telephone toll files, analytical information, and work products that are not either retained, stored, or exchanged and criminal history record information or identification (fingerprint) systems are excluded from the definition, and hence are not covered by the regulation * * *." 58 FR 48448-48449 (Sept. 16, 1993.) The comments further noted that materials that "may assist an agency to produce investigative or other information for an intelligence system * * *" do not necessarily fall under the regulation. *Id.*

The above rationale for the exclusion of non-intelligence information sources from the definition of "criminal intelligence system," suggests now that, given the availability of more modern non-intelligence information sources such as the Internet, newspapers, motor vehicle administration records, and other public record information on-line, such sources shall not be considered part of criminal intelligence systems, and shall not be covered by this regulation, even if criminal intelligence systems access such sources during searches on criminal suspects. Therefore, criminal intelligence systems may conduct searches across the spectrum of non-intelligence systems without those systems being brought under 28 CFR Part 23. There is also no limitation on such non-intelligence information being stored on the same computer system as criminal intelligence information, provided that sufficient precautions are in place to separate the two types of information and to make it clear to operators and users of the information that two different types of information are being accessed. Such precautions should be consistent with the above clarification of the rule governing the use of identifying information. This could be accomplished, for example, through the use of multiple windows, differing colors of data or clear labeling of the nature of information displayed.

Additional guidelines will be issued to provide details of the above clarifications as needed.

Richard H. Ward, III,

Director, Bureau of Justice Assistance.

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