U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

SUBCHAPTER 2.6 - COMPLIANCE ACHIEVEMENT

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2.6.1 - POLICY

FDA uses a blend of industry voluntary correction and regulatory actions to help achieve industry compliance.

A voluntary corrective action is defined as the observed voluntary repair, modification, or adjustment of a violative condition, or product. For purposes of this definition, violative means the product or condition does not comply with the Acts or associated regulations enforced by the Agency.

Voluntary destruction in lieu of seizure of small lots of violative goods shall be encouraged, where the proposed method is adequate. Supervision of voluntary segregation and denaturing of violative goods shall not be provided, except where it can be accomplished with dispatch, minimal inspectional resources, and in a manner consistent with procedures outlined in this Subchapter.

The most extensive actions in this area usually occur in disaster situations. Follow instructions in IOM Subchapter 8.5 - Disaster Procedures.

Do not engage in actual destruction, reconditioning, repair, modification, etc. of goods. This is the responsibility of the owner or dealer. You are in the capacity of witness only. Samples of violative goods should be collected prior to voluntary destruction to support subsequent action against the responsible individuals. Take photographs where applicable. See IOM 5.10.2.1 [1] and IOM 2.6.4 [2], 2.6.4.1/2 [3]or reporting requirements.

2.6.2 - DESTRUCTION

Before you supervise destruction, be sure management is aware the action is voluntary and that you are acting only as a witness. See IOM 2.6.4 [4].

Witness all destructions personally, making certain destroyed goods are rendered totally unsalvageable for food, drug, device, etc. use. Keep in mind personal and public safety. Exercise proper precautions in dealing with potentially dangerous substances and situations. Comply with local ordinances regarding the disposition of garbage and trash.

Note certain products should not be disposed of in a conventional manner (e.g.: sanitary landfill, flushing down the drain, etc.). In particular, certain products which have been banned in the past (chloroform, methapyrilene, hexachlorophene, PCB, etc.), are classified by EPA as hazardous and toxic substances and may require a special method of disposal by a licensed hazardous disposal facility. Any possible hazardous or toxic substance (carcinogen, mutagen, etc.) should not be disposed of without prior consultation by the firm with the U.S. Environmental Protection Agency [5] and/or the regulating state authority. Refer to 21 CFR 25 [6] and the National Environmental Protection Act [7] for guidance regarding the environmental impact of voluntary destructions.

2.6.2.1 - DEA Controlled Drugs

FDA and DEA have a written policy to permit FDA representatives, in certain situations, to witness the destruction of DEA controlled drugs. The procedures and instructions to follow when these drugs are destroyed are:

2.6.2.1.1 - DEA APPROVAL

FDA and the Drug Enforcement Administration [8] (DEA) have a mutual, written policy concerning witnessing the destruction of drugs under the distribution control of DEA. This provides for FDA, upon receiving a request to witness such destruction, to advise the DEA regional office and obtain approval for the action. If approval is requested by telephone and verbally approved, the approval should be reduced to writing for the record.

2.6.2.1.2 - PROCEDURE

The necessity for FDA personnel to witness destruction of DEA controlled drugs will normally happen only when FDA is already present in the firm,

encounters DEA controlled drugs, and is requested to witness destruction, or when DEA controlled drugs are to be destroyed at the same time FDA is witnessing destruction of drugs not under DEA control.

If you are in a firm either making an inspection or to witness destruction of drugs under FDA's distribution control, and the firm requests you also witness destruction of DEA controlled drugs, do not commit yourself. Telephone your supervisor for instructions. You will be advised whether or not to proceed after your district communicates with DEA. In all other situations refer the requester to DEA.

If the request to witness the destruction is approved, observe the destruction, and prepare DEA Form DEA 41[9] as follows:

1. List each dosage form of each drug on a separate line.
   Calculate amounts for columns 6 and 7.
2. Line out the inappropriate sentences in the paragraph following line 32.
3. Date and sign the form.
4. Type or print your name, title, and district under your signature.

Prepare the original only and submit it to your district for transmittal to DEA.

2.6.3 - RECONDITIONING

The supervision of voluntary segregation of violative goods without the regulatory safeguards of seizure should be avoided. Voluntary segregation and destruction of violative lots should be encouraged; but under no circumstances should you supervise the voluntary segregation and salvage of unfit goods, regardless of the nature of the violation or the size of the lot. Be sure management is aware the segregation is its responsibility. Collect samples where indicated, and/or advise the dealer or owner of his responsibilities under the law. If the dealer decides to voluntarily destroy any lot, refer him to the National Environmental Protection Act[10] (NEPA). See IOM 2.6.2[11].

2.6.4 - REPORTING

Report any voluntary correction of a problem unrelated to a district recommendation for regulatory action.

2.6.4.1 - Documenting Voluntary Destruction

Prior to supervising voluntary destruction, prepare a statement on the firm's letterhead or on an FDA 463a, Affidavit, providing the following information.

1. Voluntary nature of the action, with you as a witness.
2. Name of the product, including applicable code marks.
3. Condition of the lot.
4. Amount.
5. Method of destruction.
6. Signature of responsible individual.

2.6.4.2 - Compliance Achievement Reporting

The following are examples of compliance actions to be described in the report, EI Record, and reported into the Compliance Achievement Reporting System in FACTS (Exhibit 5-15) per district office SOP's:

2.6.4.2.1 - VIOLATIVE PRODUCTS

Voluntary destruction by the person in possession of any violative product.

2.6.4.2.2 - DESTRUCTION BY COOPERATING OFFICIALS

Destruction of violative products by a cooperating food or health official, where such product was discovered by and reported to such official by FDA when those officials were doing work for FDA under contract. Do not report formal condemnation by cooperating officials in the usual course of their independent work.

2.6.4.2.3 - MANUFACTURER'S RAW MATERIALS

Voluntary destruction of manufacturer's raw materials during the course of an inspection. For example, decomposed cream or filthy milk.

2.6.4.2.4 - CAPITAL IMPROVEMENTS

Significant improvements correcting a violative condition such as new equipment, rodent-proofing, etc. These should be reported at follow-up inspections where actual improvement has been accomplished or committed, and the improvement is the result of a previous FDA observation or suggestion and not as a result of a seizure, injunction or prosecution.

2.6.4.2.5 - CORRECTION OF GMP DEVIATIONS

During an inspection the investigator observes GMP deficiencies have been corrected since the previous EI. These corrections are based on the previous FDA 483.

2.6.4.2.6 - FORMULA/LABEL CORRECTION

Based on a sample analysis, consumer complaint, etc., a product formula or label is corrected.

2.6.4.2.7 - ADDITIONAL PERSONNEL

Employment of personnel for quality improvement or improved quality control.

2.6.4.2.8 - EDUCATIONAL AND/OR TRAINING

Initiation of an educational and/or training program among employees or producers, or other general industry movement to improve conditions.

2.6.4.2.9 - ITEMS NOT REPORTED IN FACTS

Do not report:

1. Recalls, although voluntary, because they are already recorded elsewhere (FACTS).
2. Corrections which are not directly attributable to the efforts of FDA, or states under contract to FDA.
3. Corrections as a result of a seizure, injunction or prosecution.

For products involving the field compliance testing of diagnostic X-Ray equipment, use form FDA 2473a to report these actions, as directed by the

Compliance Program. Submit the completed form to your district. Your district will submit a copy to the CDRH, Office of Compliance and maintain a copy for the district files.

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