



U.S. Department
of Transportation
**Research and
Special Programs
Administration**

MAY 19 2004

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Washington, D.C. 20590

Mr. Marc Barclay
Director, Regulatory Affairs
Helena Laboratories, Inc.
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Ref. No. 03-0165

Dear Mr. Barclay:

This responds to your letter regarding the transportation of diagnostic specimens under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask whether a diagnostic specimen is regulated under the HMR. You also inquire whether the current U.S. Postal Service's Domestic Mail Manual (USPS DMM) requirements for diagnostic specimens are consistent with the current HMR. I apologize for the delay in responding.

The answer to both of your questions is yes. Unless otherwise excepted in § 173.134(b)(6), a diagnostic specimen is regulated under the HMR and must be triple-packaged as specified in § 173.199. The current USPS DMM is also consistent with this regulatory requirement. You may review the current USPS DMM online at <http://pe.usps.gov>.

I trust this satisfies your inquiry. Please contact us if we can be of further assistance.

Sincerely,

Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards



030165

173.134 (b) (6)

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Stevens
§ 173.134
Definitions

03/1/65

Marc Barclay
Dir., Regulatory Affairs

June 30, 2003

Re: DOT 49 CFR 173.134
-- Request for interpretation
(As applied to USPS/DMM)

A concern about the appropriateness under U.S. Postal Service (USPS) of mailings for ColoScreen\ES and brand-name FOBT versions of guaiac slides is summarized here. This regards domestic mail transport of our product, post-use by a customer, as a *diagnostic specimen*.

This is a request for interpretation in response to concern about compliance with the latest revision to the DOT regulations raised by one Post Office. One USPS branch has allegedly issued a letter that indicates that mailings of this type would no longer be accepted as handled or labeled. I have reviewed Domestic Mail Manual [DMM - Issue 57 -- 2-6-03] and 49 CFR 173.134 [revised Oct 1, 2002] relative to this type material.

Device *Instructions for use* require users to apply a *very thin smear* of stool specimen to each of three guaiac paper slides, using a wooden stick the size of a coffee stirrer. The clinical specimen is absorbed onto the test paper, and is *air-dried* prior to sealing/mailing. Air-dried specimens are contained within the slide as the slide flap is closed. The slide is considered the *primary container* under U.S. Postal Service regulation interpretation. No extra or additional absorbent material is required in the packaging [DMM section C0023.8.4 a)], as the sample is not a liquid.

Slides are placed inside a poly-foil pouch, which is sealed by an attached adhesive strip. Sealed pouches act as the USPS-defined *secondary container*. This pouch routinely becomes the mailing envelope. It is labeled "Clinical Specimen" on the address-side. Pouch artwork was modified on the outside container, address-side [800140 rev. 9/01 (5)] to identify the type of specimen, *Stool Sample* [per DMM section C0023.8.7 b)].

Helena Laboratories  Helena Point of Care

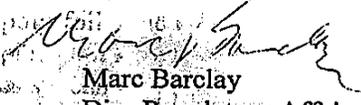
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HELENA – DOT & ColoScreen\ES/FOBT Mailings - page 2 of 2

Per my understanding, the outside mailer -- poly-foil pouch -- need not be marked with the symbol for "biohazard," as the sample is *not* known or expected to be an etiologic agent, or contain a known infectious substance. The slides are for use in detecting possible 'occult' or hidden blood in the stool. The population sampled is not at risk for any infectious disease, but are generally over 50, or have a personal or family history for polyps or G.I. disease, such as colorectal cancer.

Our product has been on the market for twenty-three years -- and for competitor products, even longer. Untold numbers of lives have been saved from colorectal cancer since then, due to early diagnosis and providing treatment at curable stage.

Does DOT consider this material to meet the definition of *diagnostic specimen*, and thus, an exception to other requirements under this part?



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