TO: DR. von ESCHENBACH Andy

FAX: 301 827-6870

FROM: JAMES L. GAJEWSKI, MD, FACP

DATE: February 20, 2007

SUBJECT: DOCKET: 2005N-0403 and RIN 0910-AA49. Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs

Temporary Comment Number: 111705

2005N-0403

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Docket Management Comment Form

Docket: 2005N-0403 - Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs

Temporary Comment Number: 111705

Submitter: Dr. James Gajewski **Date:** 02/20/07

Category: Health Professional

Issue Areas/Comments

General

Dear Dr. von Eschenbach, As you recall from our days working together at the U.T. M.D.Anerson Cancer Center, the issues regarding hematopoietic progentor and stem cell transplants have not easily fit into beaurocratic categories. I have always been concerns that HHS has not been speaking with one voice regarding the cells I transplant. FDA has increased our safety surveillance and yet CMS refuses to recognize as valid CPT codes 38207, 38208, 38209, 38210, 38211, 38212, 38213, 38214 and 38215 so I can properly bill allpatients for the processing of teh cells we in the BMT field tranplant. In this letter, I am responding as a concerned health care professional and not as a Temple University faculty member and also not as a member ofa professional society. As you personally know, I have had extensive experience in the regulation issues affecting the cells I and others in the BMT field transplant. I am certain you recall that above all else I care about clinical excellence and tolerate less than comprehensive clincial excellence poorly. Licensing each product collected will add to our papaer work and cannot be done in real time between collection and infusion. Because bone marrow is exempt from these regualtion because of regulartory burden physician may opt to choose one type of collection over another. Many institutions infuse these products fresh so there is not 24 hours time to obtainan FDA registration ofan individual product. We are required under FDA regulations in CFR 1271 that went operational on May 25, 2005, to label products and validate all items quantified on the label. FDA registration of an individual products adds to the reporting burden without changing the mandate of quality. Many centers have had problems tracking the lot numbers of hematopoietic growth factors used in the days prior to apheresis collection of hematopoietic progenitors as well as the alcohol wipes. The health payment system with private and governmental payers often require different administrators of these services than the institution doing the apheresis. As you are aware any product deviation or toxicity under the FDA regulations in CFR 1271 which went operational on May 25 2005 are regquired to be reproted to FDA. Licensure of individual products adds nothing to the public safety and does not help us track toxicities any better. As an old friend thank you for the opportunity to comment here. Please also at inter agency meetings with CMS encourage CMS to allow us to bill for services required by FDA for cell processing. James L. Gajewski, MD FACP

Attachments

No Attachments

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processes and initiatives that can add to patient safety.

Your Voice Is Needed

A provision in the proposed rule allows the FDA to grant exemptions. You can help claim an exemption for HPC products by your communication to the FDA.

Personalize your comments by explaining why, from your perspective and experience, the proposed National Drug Code system would be troublesome to your practice and potentially harmful to your patients. Be constructive. The agency is trying to enhance patient safety but needs to understand the negative implications of the proposed coding system for HPC products.

As noted above, you can click here to submit a comment to the FDA docket or fax a letter to (301) 827-6870. If you send a fax, mention Docket No. 2005N-0403 and RIN 0910-AA49.

Thank you.