David Pollock - FW: adhesive

From: "Nojek, Thomas W" <thomas.nojek@fda.hhs.gov>
To: "'pollockd@childrensdayton.org'" <pollockd@childrensdayton.org>
Date: 8/28/2006 10:11 AM
Subject: FW: adhesive

David:

I received this last week and apologize for the delay in forwarding it to you. Nancy Neiger is our BB Specialist for the Cincinnati District and works out of our Cleveland Office. Gail Katz is one of the Whiz Kids in CBER. So, you have it on good authority that there are no FDA compliance issues with placing Avery labels on blood products. At this time anyway.

Tom

Thomas W. Nojek
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Cincinnati District Office
6751 Steger Drive, Cincinnati, OH 45237
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From: Neiger, Nancy L
Sent: Wednesday, August 23, 2006 10:41 AM
To: Nojek, Thomas W
Subject: FW: adhesive

Hi

I just got a call from Gail Katz, DFI regarding the adhesive on the labels. She said that the Avery labels are fine. They could use those. She also said that if they put it on the existing label it helps with the adhesive. Just as long as they don't cover up other info. But they can also put the Avery labels on the bag directly.

I hope this covers it. If I can help with anything, let me know.

Nancy

From: Neiger, Nancy L
Sent: Friday, August 18, 2006 9:51 AM
To: Nojek, Thomas W
Subject: RE: adhesive

It's a 2002 e-mail so I'm sure the person is no longer there. They seem to come and go quickly at CBER. I sent an e-mail regarding this issue to CBER so hopefully we'll get a quick response.

I'll let you know what I hear.

Nancy

From: Nojek, Thomas W
Sent: Friday, August 18, 2006 9:21 AM
To: Neiger, Nancy L
Subject: FW: adhesive

Nancy:

David Pollard, the person I've been talking to about BB labeling sent me this e-mail concerning labeling. I could not find Sukza Hwangbo listed in the FDA's e-mail data base.

Tom

From: David Pollock [mailto:PollockD@childrensdayton.org]
Sent: Friday, August 18, 2006 9:00 AM
To: Nojek, Thomas W
Subject: adhesive

Tom,

I got this from this website: http://www.cbbsweb.org/enf/2002/adhesiveleach.html

A blood banker from Virginia wrote that they received the following e-mail from Sukza Hwangbo of the **FDA** regarding blood bag labels:

"We receive queries from blood label manufacturers, toxicology testing lab, and blood establishments. I hope the following statement will help those inquirers understand the issues surrounding blood bag labeling:

Adhesives from labels or other device components may leach into stored blood, and they should be evaluated for a potential health hazard. Applicants should submit data, including that for the extractability of individual adhesive ingredients, and provide an acceptable safety analysis on recipient exposure.

In certain cases, when the levels of the extractable are so low that they are impossible to measure, applicants often submit their analysis of recipient exposure extrapolated from a worst-case scenario, assuming that the entire amounts of the chemicals used in the formulation were leached into the blood.

The substances listed in the CFR Part 175.105 are chemicals that have been approved as components of articles intended for use in packaging, transporting or holding food. For the labeling of blood and blood components, the substances listed in the above CFR may be safely used when formulated as adhesives applied on secondary labels that will be placed over the original base label. For labels directly applied on the surface of blood bags, we require additional info.

When primary labels are reviewed as a part of a New Drug Application, e.g., a blood collection bag with anticoagulant solution or as a part of a device submission, e.g., a transfer bag, the FDA evaluates the safety as well as effectiveness of those articles used in primary labels by reviewing their formulations and performance data. The effectiveness of an adhesive is measured as the adhesion performance and readability evaluated under different storage conditions, e.g., condensation, smear, etc. The type of plastic film can affect the

performance of adhesives.

The requirement to submit safety data may be waived for products using previously cleared adhesives, provided that appropriate references are included in the submission. We recommend that blood establishments who wish to use labels for direct use on blood bags (primary labels) select labels whose adhesives and inks have been reviewed by the FDA for their safety and effectiveness either under a new drug application, Masterfile, or a device submission.

We recommend that label manufacturers and toxicology labs review the safety data requirements listed in USP as well as in the ISO-10993, "Biological Evaluation for Medical Devices Part 1: Evaluation and Testing."

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