From: OC GCP Questions
To: [redacted]
Subject: question about minimal risk NSR dev ce studies at continuing review
Date: Wednesday, January 28, 2015 9:04:02 AM

Good morning [redacted]--

I apologize for the delay in responding to your question. We generally return responses in less than a week. Your email generated a lot of discussion among many individuals. Please see Soma's response below. She is the Director of the DE staff at CDRH.

Again thanks for your patience.

Kind regards,

Doreen M Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10 85, but rather is an informal communication under 21 CFR 10 85(k) which represents the best judgment of the employee providing it This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed

---

From [redacted]
Sent: Tuesday, January 27, 2015 4:21 PM
To: [redacted]; OC GCP Questions
Cc: [redacted]
Subject: RE: question about minimal risk NSR device studies at continuing review

Dear Doreen,

Thank you for this inquiry I apologize for the delay After discussing with IDE staff, BIMO, and Joanne Less, our response is as follows

An NSR study that is determined to be minimal risk by a convened board *would* be eligible for expedited review for continuing review under Category 9 Our interpretation is that NSR studies are not conducted under an IDE [application], and therefore, not disqualified from Category 9 NSR studies are "considered to have an approved IDE" for the purpose of shipping an unapproved device and the manufacturing requirements, but they don t actually have an approved IDE application, which is required only for SR studies/devices

Those with whom I discussed this inquiry are copied here and are welcome to add any clarifying language

Thanks,

Soma Kalb, PhD
Director, IDE Program
soma kalb@fda hhs gov
Phone: 301-796-6359

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www research net/s/cdrhcustomerservice?O=400&D=410&B=412&E=&S=E

From: [redacted]
Sent: Monday, January 05, 2015 8:18 PM
To: OC GCP Questions
Subject: Re: question about minimal risk NSR device studies at continuing review

Thank you for the update Would it possible to let me know if the CDRH had a chance to review my inquiry? My question relates to whether or not NSR device studies can meet any of the expedited review categories at the time of continuing review (i e , would it be eligible for expedited review category 9 or another category)?
Kind regards,
[redacted]

On Thu, Oct 30, 2014 at 1:16 PM, OC GCP Questions <gcp questions@fda hhs gov> wrote:
Good afternoon –

I wanted you to know that I sent your question to the Center for Devices (CDRH). They stated that they won't be able to respond until the middle of next week as they need to confer with others in the Center. I apologize for the delay.

Kind regards,

Doreen M Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10 85, but rather is an informal communication under 21 CFR 10 85(k) which represents the best judgment of the employee providing it This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed

From: [redacted]
Sent: Tuesday, October 28, 2014 6:30 PM
To: OC GCP Questions
Subject: question about minimal risk NSR device studies at continuing review

Dear Office of GCP:

If an NSR device study is deemed minimal risk by the convened Board, then would the study also not be eligible for expedited category 9 at continuing review if the study remains open to enrollment and subjects are still receiving research-related interventions? This would seem consistent with the answer provided by the Office of GCP in the attached email regarding category 1B which explains that an abbreviated IDE is considered by FDA as having an IDE application
Thank you,
[redacted]