Transcript for the FDA Media Briefing on the McNeil Product Recall
May 4, 2010

Coordinator: Welcome and thank you for standing by.

I'd just like to inform all participants that your lines have been placed on a listen only mode until the question and answer session of today's conference.

Today's call is also being recorded. If you have any objections you may disconnect at this time.

I would now like to turn the meeting over to Ms. Elaine Gansz Bobo. Ma'am you may begin.

Elaine Gansz Bobo: Thank you very much everyone for joining us today. And our apologies for starting a little bit late. But we're glad you're all here.

I'm Elaine Gansz Bobo from the FDA's Office of Public Affairs.

And we want to welcome you to this briefing on McNeil Healthcare Recall and FDA's Inspection Report.

Our speakers this afternoon are Dr. Margaret Hamburg, who's Commissioner of FDA, Mike Chappell, our acting Associate Commissioner for Regulatory Affairs, and Deb Autor, Director of the Office of Compliance within the Center for Drug Evaluation and Research.

We'll have a brief question and answer segment after the opening remarks. And at this time I'd like to turn it over to commissioner Hamburg.

Commissioner.

Margaret Hamburg: Thank you very much. Good afternoon. We appreciate your joining in this call. We wanted to take this opportunity to provide some updated information as well as some important public health advice.

As you all know McNeil Consumer Healthcare implemented a voluntary recall of infant and children's liquid products due to manufacturing deficiencies which may affect the quality, purity or potency of their products.

I want to take this opportunity to underscore some important messages for consumers and in particular for parents.

Please discontinue using any of the name brand products being recalled. A comprehensive product list is located on the FDA Web site.

While the potential for serious health problems is remote, Americans deserve medications that meet FDA standards for quality, safety and efficacy.

There are many alternative versions of these medications available in generic form. Your pharmacist can help you find the one that's right for your child. And parents should not get infants and children medications not intended for their particular age group. Because this is a large scale recall of more than 50 over-the-counter medications for infants and children this action has generated a great deal of interest from consumers and the media.

Today we're posting the inspection report of the McNeil plant on the FDA Web site. We thought it would be important to put those findings in a proper perspective so we arranged this call in order to give reporters access to some of the senior agency leaders who can help explain more about the inspection findings at the McNeil plant and any other information that you might be interested in.

But before getting into the specifics I want to turn the microphone over to Deb Autor, the Director of the Office of Compliance and FDA Center for Drug Evaluation and Research.

And I want to apologize that I'm not going to be able to remain on the line for the question and answer period.

But I know that my colleagues will be able to answer the questions that you may have so thank you very much for your time and attention on this important issue.

Deb Autor: Thank you Dr. Hamburg. This is Deb Autor, Director of the Office of Compliance and FDA Center for Drug Evaluation and Research.

I want to provide the press a high level summary of the report we've just posted and of the current situation regarding McNeil.

Today FDA has posted the investigators' findings from the just concluded inspection of McNeil's Fort Washington, Pennsylvania facility where the recall products were made.

I want to emphasize that this is just a report of the investigators' observations. The investigators are currently preparing the full narrative regarding their inspection which the agency will then evaluate.

The report posted today cites numerous deficiencies in the ways in which McNeil's products were manufactured in which the manufacturing process for those products was controlled.

Most significant deficiencies relate to the firm's failure to sufficiently investigate and correct problems found in its manufacturing and in its drugs. Changing the manufacturing process without assuring the change would not harm the quality of the drugs and not maintaining proper facilities and procedures for testing drugs.

As mentioned this report is a list of what the investigators saw on inspection. The agency is now further evaluating these findings and will evaluate the narrative provided by the investigators to make a final conclusion about how serious the findings are and whether FDA should take further regulatory action.

The agency's initial assessment is that the findings are serious but we cannot yet say whether further action by FDA is warranted.

In February of this year FDA met with high level management of McNeil and of its parent company, Johnson & Johnson, and we expressed the agency's serious concerns about McNeil's manufacturing operations.

Since that time McNeil has taken actions to improve. FDA does not yet know whether those actions were sufficient and whether further action by FDA is needed.

FDA is in regular contact with McNeil. The company has shut down all manufacturing at the Fort Washington plant and has committed that it will not resume manufacturing at that facility without notifying the agency.

I just want to conclude by stating that this is yet another example the need for companies to take full accountability for the quality of the drugs and of the serious consequences that can happen when companies do not do so.

Elaine Gansz Bobo: Thank you very much Deb. And at this time ladies and gentlemen we'll take your questions.

And as always if you could please limit yourself to one question and one follow-up. And if you could please, state your name and affiliation.

Operator we'll take the first question.

Coordinator: Thank you. Our first question comes from Rita Rubin. Your line is open.

Rita Rubin: Hi. Thanks for taking my call. I wondered if you could just go over the timeframe a little. Ms. Autor, I'm sorry I missed when you said FDA officials had first met with McNeil officials.

And also are these - if the plant is shut down and all the plant made was these products the ones that have been recalled, so I don't know where, you know, like adult strengths, Tylenol and Zyrtec and the other products are made or is that at a different plant?

Deb Autor: Okay, well again the meeting with the firm was in February. And the inspection was conducted in April of this year, started April 19 and was concluded on April 30.

With respect to the facility, they do - McNeil does also make solid oral dosage forms at that facility. They have shut down the manufacturing of those products as well.

But at this point there has not been a conclusion that those products need to be recalled.

Rita Rubin: Do they make them somewhere else or that's it, that's the only place they make the solid dosage forms?

Deb Autor: I believe they do have another facility where they make those products. That's - would be a good question for the company to answer as well.

Rita Rubin: Okay, thank you.

Elaine Gansz Bobo: Our next question.

Coordinator: Our next question comes from (Jennifer Corbett). Your line is now open.

Jennifer Corbett: Yeah. Hi. Thanks for taking my question. I noticed on Observation 1 on the report they talked about - I mean our version is pretty blacked out but it says raw material was contaminated.

So I guess I'm wondering if you can explain what that means. To me that means that the - that some Tylenol is contaminated.

Mike Chappell: Yes. So this is Mike Chappell. I'm the acting Associate Commissioner for Regulatory Affairs.

And your question is regarding the first observation which really is pointing to the responsibilities of the Quality Control Unit to make sure that appropriate controls are in place for raw materials that are coming into the facility.

And indeed the observation talks about known contaminants and those known contaminants are gram negative organisms.

Jennifer Corbett: But can you say what that means, I mean for consumers? Is that - I mean the agency said that they think that the - I guess health risks are pretty remote. But is there like a low level of contamination in the Tylenol or can't you say yet?

Mike Chappell: The observation relates to the raw material. I don't have information related to the product itself.

One of the concerns of course is contamination in general but then also as you pointed out the type of organism, etcetera. I don't have that information.

Jennifer Corbett: Okay.

Elaine Gansz Bobo: Our next question.

Coordinator: Our next question comes from Susan Heavey. Your line is open. And please state your affiliation.

Susan Heavey: Hi. I'm with Reuters. I had a question for Page 5, Item Number 2. It says and this is Page 5 of the Adobe version. That the firm's investigation into recall

for various Tylenol products containing did not include a review of all lots received from the contract manufacturer.

Can you explain that a little bit? What recall is it referring to? And I mean it sounds like the inspectors are saying that there were previous recalls and that in investigating those J&J did not look at all the lots that could have been affected.

Mike Chappell: Again this is Mike Chappell. Let me express that the purpose of the comment (unintelligible) observation, that was that when a problem is found in a manufacturing facility one, that does lead to a recall, one of the responsibilities of the firm is to determine the root cause of that problem and then any other lots that could have been implicated by that same concern.

The observation and I'm sorry, I can't match my list with yours, but based on your read of that to me is that there was in investigating this there were probably other things that the firm could have done and should have done as far as the root cause goes to make sure that all of the raw materials that were involved in that recall were not used for manufacturing other products.

Susan Heavey: That's Observation 6 by the way if that's helpful. It's under that section.

Elaine Gansz Bobo: Okay, is there another question?

Coordinator: Yes, our next question comes from Nancy Layton. You may ask your question. And please state your affiliation.

(Nancy) Layton: Hi. Thanks. I'm from the Washington Post. And I guess I'm just following up. Mike I'm a little confused when you talked about the gram negative organisms, is this bacteria? Can you just give us some sense of what, you

know, gram negative organism. What would that be? Would that be the bacteria or the black particles or can you just please clarify that a little bit for us?

Mike Chappell: Right. And there are certain microbiological tests that determine that you have a certain category of organism. It does mean a microorganism. There are many gram negative organisms.

The observation here is that the firm had determined there were gram negative organisms. But they did not - this particular observation did not (unintelligible) the (unintelligible) implication of the organisms but it is a microorganism.

Nancy Layton: Okay. Can I ask a follow-up question as well?

Elaine Gansz Bobo: Absolutely Nancy.

Nancy Layton: So the 483 says that McNeil received 46 consumer complaints over approximately the past year.

And did the FDA also receive some of these complaints?

Elaine Gansz Bobo: Deb is that a question for you?

Deb Autor: I'm sorry. Could you repeat the question?

Nancy Layton: I just am wondering the company received consumer complaints about the specs and the black particles in the children's Tylenol.

Was the - did the FDA also receive some of these complaints?

Deb Autor: Yeah, we're looking into that now. We do have a system in which consumers report complaints they have about drugs and we've actually encouraged consumers to report to MedWatch now any complaints they have about McNeil products.

But I can't answer today as to the exact match up between information McNeil had and we might have had. I would say though that I think that the term bacteria would be appropriate for the gram negative organism that's mentioned in the report.

Nancy Layton: Thank you.

Elaine Gansz Bobo: Next question.

Coordinator: Our next question comes from Matt Perrone with AP.

Matt Perrone: Hi. Thanks guys. As far as the gram negative organisms, the bacteria, whatever we want to call it, do we know whether that ever made it into the actual products or it's not really clear from the report?

Mike Chappell: Again I'm going to go back and talk a little bit about the list. These are actually a list of observations. There are very specific observations that are made during the course of this inspection. This particular list of observations will include a narrative report. That narrative report will go into specific details about the relationship of this item to other items on the list and also any other documentation that the investigator collected during the course of the inspection. That's why trying to read a 483 by it self and understand the significance is difficult without the finished narrative.

Matt Perrone: I see. It sounds like we don't know.

My second question, what prompted this inspection? You mentioned you've been talking with J&J management back in February. Was this tied to their last recall back in January?

Deb Autor: Well this was a regular inspection of this facility. As you know we do conduct regular inspections of drug manufacturers. And when we go to each facility depends on such factors as specific problems we have found at that facility in the past, the facility's manufacturing history, the medical importance of the products made there and also how difficult it is to make those products well.

So putting all these criteria together this facility was due to be inspected and we inspected them.

Mat Perrone: So this didn't have to do with the conversations you were having back in February. I wasn't sure.

Deb Autor: Well as I said, one of the factors that can be used in determining where we go when is the firm's inspection history. And that did in fact drive us to inspect this facility more quickly.

Matt Perrone: I see. Okay, thanks.

Elaine Gansz Bobo: And I believe we have a follow-up answer to that as well if you could introduce yourself.

Douglas Stearn: Yes, this is Douglas Stearn. I'm the Assistant Director of the Office of Compliance in the Center for Drug Evaluation and Research. There was an earlier question about whether or not FDA had information about

contamination within product that was finished product samples or what has been released to the market.

Our information is that none of the finished product samples tested by McNeil were positive for the contamination you referenced.

Matt Perrone: Okay.

Elaine Gansz Bobo: Good. We can take the next question.

Coordinator: Thank you. And as a reminder, please press star 1 if you would like to ask a question.

Our next question comes from Jonathan Rockoff with Wall Street Journal. Your line is open.

Jonathan Rockoff: Have you received any reports of side effects? Of adverse events?

Douglas Stearn: This is Douglas Stearn again. We are reviewing as Ms. Autor earlier mentioned, we're reviewing what has been reported to the agency. Right now we do not have positive identification of a causal link between adverse events and the manufacturing deficiencies that have been referenced here.

But we still need to do that review in order to have a more definitive conclusion.

Jonathan Rockoff: Thank you.

Elaine Gansz Bobo: Do we have another question?

Coordinator: Yes. Our next question comes from Natasha Singer with New York Times. Your line is open.

Natasha Singer: Thanks. This is a follow-up question about the bacteria and whether we know whether it's in the products or not because in Observation 6 Part 2, it says that review of the vendor lots found that they contained drugs contaminated with gram negative organisms. And then it goes onto say that those vendor lots were used to manufacture the following Tylenol infant's and children's products which were marketed and remain.

And then it lists all the ones that were made using the vendor lots that were contaminated.

So I guess I would like you to confirm that in fact the contaminated raw materials were used to manufacture the lots that you've listed here.

Douglas Stearn: Yeah, this is Douglas Stearn. I guess what I would say is that what we are talking about is risk. You've asked about, you know, what we know. What we know about first as Mr. Chappell mentioned earlier, there's been an observation about their practices and part of the concern may be related to whether their practices provide consistency in terms of quality and create a potential risk for contamination.

What we earlier described to you is what we knew about from the product testing.

So product testing provides us some information. But we can't - not every single thing gets tested, every single - in terms of everything on the - in terms of all knowledge that we might have.

So what we're talking about is a potential risk. We've described overall the risk here as remote in terms of serious adverse health consequences.

Deb Autor: Yeah, just to sum it up. So in this case McNeil purchased lots of excipients meaning line an inactive ingredient from a vendor. Those vendor lots tested positive for the bacteria but McNeil's finished product did not.

Natasha Singer: But they were used to manufacture the finished products anyway.

Deb Autor: Yes.

Natasha Singer: Okay, so contaminated materials were used to manufacture the products. However testing has not shown the product themselves to be contaminated.

Deb Autor: Potentially contaminated materials were used.

Natasha Singer: This says known contamination.

Deb Autor: Certain lots of that excipient had tested positive for bacteria.

Natasha Singer: Okay.

Elaine Gansz Bobo: Okay, if we could have the next question.

Coordinator: Next question comes from Susan Schwartz with ABC News. Your line is open.

Elaine Gansz Bobo: Susan, are you there?

Coordinator: Susan, please check your mute button.

Elaine Gansz Bobo: Okay, is there a question from Susan Schwartz?

Rich Besser: Yeah, can you hear me now?

Elaine Gansz Bobo: We could take the next question then.

Rich Besser: Yeah hi. It's Rich Besser on Susan Schwartz's phone.

Elaine Gansz Bobo: Go ahead.

Rich Besser: ABC News. Can you hear me?

Elaine Gansz Bobo: Rich go ahead. Can you hear us?

Rich Besser: Yeah hi. Thanks very much. Yeah, Deborah Autor had commented that the findings were quite serious and that FDA would consider whether further regulatory actions warranted.

What type of actions would FDA be considering taking?

Deb Autor: Well our tools include sending warning letters, seizing products, seeking a court order from a firm - and joining a firm in some way for manufacturing or to take certain corrective actions and criminal penalties.

And we would consider the full range of available tools to decide what if anything is appropriate.

Rich Besser: Okay. My other question comes back to that February meeting. What led to that February meeting? Did FDA receive consumer complaints or have other concerns that led to that meeting?

Deb Autor: Well as you may know we sent the firm a warning letter in January of this year. And while that warning letter related primarily to a different facility it did express FDA's concerns about the entire company's control over the quality of its drugs and the company's failure to aggressively investigate and correct quality problems.

So as I said we met with the firm. We met with high level management. We expressed our concerns. And the firm has made some changes.

But that warning letter brought us to a point where we felt it was necessary to sit down with high level management and to express that we had serious concerns.

Rich Besser: Thanks very much. I appreciate it.

Elaine Gansz Bobo: Okay, we'll take the next question.

Coordinator: Next question comes from (Pamela Iraq), CBS News. Your line is open.

(Pamela Iraq): Dr. Besser just asked my question.

Elaine Gansz Bobo: Okay, if we have - next question then please.

Coordinator: Denise Mann from WebMD. Your line is open.

Denise Mann: Hi. My question is basically for concerned parents. I mean a lot of times when there are recalls you are told that you should just look at the serial or lot numbers and those are the ones that you should throw away.

You're basically saying that any of these medications need to be thrown away.

So my first question is, you know, what should I be telling parents? They're obviously concerned.

And are there generic versions for all of these?

And how can I really sum up what the risk might be to their children if they continue to use something they've been using, you know, for the past month or so? If let's say it was an allergy season like the Zyrtec.

Deb Autor: Yeah. Well these products - consumers should not use these products. There's information on McNeil's Web site about what to do if you have these products. But consumers should not use them. And by all means consumers should look for generic versions of the products to use. There are generic versions available of these products.

And another important note of caution that Dr. Hamburg mentioned is that consumers should not give drug products to infants and children that are not intended for those age groups.

And as we said we do think that the likelihood of serious adverse events is remote. If a consumer has given these products to - if a parent has given these products to a child and hasn't seen any adverse events, then that probably means there's not much reason for concern.

But at this point I would advise that they discontinue using the products and seek alternate treatments.

Elaine Gansz Bobo: Could we go to the next question?

Coordinator: Next question comes from Andrew Zajac from LA Times. Your line is open.

Andrew Zajac: Hi. What is the bacteria?

Deb Autor: I don't think we're prepared to say that at this point.

Andrew Zajac: Why not?

Deb Autor: We don't have full information yet.

Mike Chappell: Yeah, the - this is Mike Chappell again. Just to say that again the gram negative organism is a class of organism. And it can be determined that the organism is gram negative. And if that's the extent of the testing that's done you're not able to especiate the organism and say exactly which organism it is.

And that's the case in this observation.

Andrew Zajac: Can you give any indication of a family or a grouping? I mean you must know something about it?

Mike Chappell: We know it's a gram negative organism.

Elaine Gansz Bobo: If we could take the next question.

Coordinator: Next question comes from Joanne Silberner from NPR. Your line is open.

Joanne Silberner: Yeah. Hi, thanks. The question is you said the word remote, that there's a remote - it's only remote possibility that there's a problem here. You're saying that there's possible bacterial contamination. You're saying that there are also things in the product that shouldn't be there.

How does that translate to a remote chance of problems?

Deb Autor: The problems that we have actually seen in products that are on the market are ones that we do not believe will cause a significant medical concern. We have not see problems in products that we believe do cause a significant medical concern.

So based on what we've seen we don't have concrete information to believe that there's a serious medical concern. We have theoretical concerns which makes the possibility of a serious medical concern remote.

Joanne Silberner: Okay, thanks.

Elaine Gansz Bobo: Our next question.

Coordinator: Tom Maugh from Los Angeles Times. Your line is open.

Tom Maugh: I'm having difficulty finding what you posted on the Web site. Can you give me a hint about where to look for it?

Elaine Gansz Bobo: Mr. Chappell.

Mike Chappell: You know that's a good question. I appreciate that. I - it's posted on the FDA Web site but I don't - I'm not in front of a computer to tell you how to get there.

Douglas Stearn: This is Doug Stearn. I think I've checked this out a couple of times. If you're on the Web site, there's a new citation of recent news right under - right on the main page in the center column. And if you look down I think it would have been posted either April 30 which, you know, this happened the night of the April 30 or May...

Woman: Night of the 30th.

Douglas Stearn: I'm sorry. Are you talking about the 483?

Elaine Gansz Bobo: Tom this is Elaine Gansz Bobo.

Douglas Stearn: Sorry.

Elaine Gansz Bobo: I'll follow-up with you after this call and send you...

Tom Maugh: Okay, great. Thank you.

Elaine Gansz Bobo: Did you have a follow-up Tom?

Tom Maugh: No.

Elaine Gansz Bobo: Okay. We'll take the next question.

Coordinator: Next question comes from (Darren Schiff) at (Tan Sheet). Your line is open.

(Darren Schiff): Guys, thanks for taking my question. I was just wondering if you can estimate the number of product lots or product units involved in the recall.

Deb Autor: About 1,500 lots.

(Darren Schiff): Okay. And do you have a timetable for the release of the finished inspection report?

Mike Chappell: This is Mike Chappell again. The investigators are working on that report as we speak. It will then be reviewed by the District Management and others. It has always given us - we always give it a priority but I can't tell you it'll be one, two, three days. And we will give it priority.

(Darren Schiff): Thank you.

Elaine Gansz Bobo: Okay, our next question.

Coordinator: Next question comes from Tom Costello, NBC News. Your line is open.

Tom Costello: Thank you. I just want to clarify. Is there any suggestion, any hint, any concern that the contamination may have been on purpose?

Deb Autor: No.

Tom Costello: And would you tell - would you say, how would you rank the seriousness for the layperson of this bacteria?

Deb Autor: I don't think we're prepared to rank it. I think as we said we think that the risk to consumers at this point is remote.

Tom Costello: Thank you.

Elaine Gansz Bobo: Our next question.

Coordinator: Next question comes from Jennifer Smith from Pharmawire. Your line is open.

Jennifer Smith: Hi. I just have a quick question. Do any of the recalled products contain dextromethorphan?

Deb Autor: I don't think so, Tylenol, Motrin, Zyrtec and Benadryl.

Jennifer Smith: Okay, that's it.

Elaine Gansz Bobo: Okay our next question.

Coordinator: As a reminder if you'd like to ask a question on the phone please press star 1. Please unmute your phone and record your name; just a moment.

Elaine Gansz Bobo: Is there another question?

Coordinator: Yes, one moment. Peggy Peck from MedPage Today, your line is open.

Peggy Peck: Yes, hi. I know that you don't know exactly long it will take to complete this report.

But I'm wondering if you have some sort of a ballpark figure, how long you would estimate it would take for these - for the problems at this manufacturing plant to be corrected and for manufacturer of these OTCs to once again begin.

Deb Autor: That's really within the control of McNeil. And I think that that may be a question probably directed to them.

Peggy Peck: Okay, thank you.

Elaine Gansz Bobo: Our next question please.

Coordinator: Our next question comes from Valerie Levesque from CBS 3. Your line is open.

Valerie Levesque: Okay, thanks for taking my question; quick question about the Fort Washington plant. Was that shutdown imposed by the FDA or was it voluntary?

Douglas Stearn: This is Douglas Stearn. It was a voluntary shutdown.

Valerie Levesque: Okay, thank you.

Coordinator: Next question comes from Lisa Gill, Consumer Reports. Your line is open.

Lisa Gill: Hi. I just had one question. Is there any concern by the FDA that the contaminated raw materials that were purchased by McNeil might actually wind up in other drugs like for example generic versions of these drugs?

Deb Autor: We will of course be following up to make sure that the quality of all products is (ensured).

Lisa Gill: So can we basically tell consumers that it's okay to buy the generic versions and that they should reasonably be safe?

Deb Autor: Well we don't have any reason to have concerns about those products at this point. We're of course investigating to make sure that the problems we find at one facility could not impact other products. But at this point there's no reason for concern about the other products.

Elaine Gansz Bobo: Our next question please.

Coordinator: Next question comes from Cindy George, Houston Chronicle. Your line is open.

Cindy George: Yes. I had a two-part question. The first was about how many individual products are in a lot? And where were these lots distributed? Were they all over the country or in certain regions or that kind of thing?

Deb Autor: Well I can tell you that the products were distributed around the country and also to other countries internationally.

And with respect to how much is in a lot, I'm not sure offhand. You could check with McNeil and also in McNeil's press release I think they've talked about how wide the distribution is of these products.

Cindy George: Thank you.

Elaine Gansz Bobo: Okay, and if we could take our last question now please.

Coordinator: Rita Rubin from USA Today. Your line is open.

Rita Rubin: Thanks for taking my call again. A quick question is this - contamination was found in raw materials. Isn't it logical to think that it would have entered some of the adult strength products? I mean are they just totally separate? Do they -

does adult strength Tylenol not use the same raw materials as the children's and infant's versions?

Deb Autor: Yeah, these were raw materials used in liquid products, not in solid products.

Rita Rubin: Okay, thanks.

Mike Chappell: Yeah. And this is Mike Chappell again. I just want to go back to that observation that all of these liquid children's products that may have contained some of this raw material are under recall and they are being recalled by the firm.

Rita Rubin: Thank you.

Elaine Gansz Bobo: Okay.

Deb Autor: And just one correction too for Jennifer Smith's question I believe about dextromethorphan, there are in fact some products, some of the cold products that do have dextromethorphan in them.

Elaine Gansz Bobo: Okay, well ladies and gentlemen that concludes our media teleconference today.

For those of you who did get answers from Douglas Stearn I wanted to spell his name for you. Last name is S-T-E-A-R-N.

The replay of this will be available in about an hour and will be up until May 12. To hear the replay U.S. Callers can dial 1-800-756-1515 and the pass code is 5689.

If you have any follow-up questions please don't hesitate to call the Office of Public Affairs.

And we thank you very much for participating today.

Coordinator: Thank you so much for participating in today's conference call. You may disconnect your lines at this time. Thank you. And have a great day.

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