Final 10/8/03 1b

ENDOTEC
50 South Center Street, Unit 10, Orange, New Jersey 07050 • (973) 672-9300 • (973) 672-3939

5480 '03 AUG 27 A9:22

August 25, 2003

Re: Second request to expedite the appeal for the revocation of the application of the AIP (FR 10.25)

The Commissioner
Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 4-62
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner,

It has been more than six months since we requested that you expedite our appeal of March 11, 2002 to revoke the determination made by the Food and Drug Administration that the provisions of the Application Integrity Policy (AIP) (also known as the Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities Policy) should be applied to Endotec, Inc.

It has been eighteen months since we appealed to your office and our request, six months ago, for expedited action has not produced any results apparent to us. Such delays without any apparent significant steps of which we are aware seems to indicate that there is no viable appeal process for us within the FDA.

Our problem was not one of fraud but of personnel and system failures. An appropriate response of the FDA should have been corrective in nature not punitive. If the FDA had followed its stated policy, and informed us of the failures on which the AIP is based, before applying the AIP the corrective measures would have been initiated. Instead the FDA clearly violated its stated policy and applied the AIP without prior notification preventing corrective action before punitive measures were taken. Clearly this is improper. Why should it take so long to take action on our appeal? Our position on this matter is given in our letter of April 30, 2002, which is enclosed as Attachment A for your reference.

In my opinion the FDA's position with regard to us and to mobile bearing ankle devices adversely affects the welfare of the people the FDA is obligated to protect. Furthermore, this position also adversely affects the FDA itself. Mobile bearing devices of the type denied patients in the USA are routinely used in Europe while those types that the FDA allows are not. This is true since the effects of an apparently initially erroneous and certainly currently obsolete FDA classification,

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9-8-03

1) Spoke w/ Les Weinstein who referred me to Laurie Lenkel FDHs OM Budsman

2) Spoke w/ Laurie re: submission

3) Suggested should be amended to become an OP & that it is public info. However if not what should I do with it?

which we have asked the FDA to correct does not inhibit European surgeons. Experience has taught these surgeons that mobile devices are better. This has been made clear at several, recent, international conferences on ankle replacement, papers from which are enclosed (See Attachments B & C). In particular, Dr. Rippstein in his paper cites the FDA as the reason for the difference in ankle usage between the USA and Europe. It appears that where a surgeon is free to choose they will select devices, the sale of which the FDA prevents. Do you think this situation does credit to the FDA?

Furthermore, the FDA promotes an apparently dangerous device (see Attachment D as the most recent example), which meets its obsolete classification criterion by allowing its sale and by recommending it directly in letters to patients (please refer to the enclosed FDA letters to patients and legislators, Attachments E & F). As Rippstein points out only the Agility is used in our country because of the FDA. Do you think such action does credit to the FDA?

We see the actions of the FDA in this whole matter as damaging to everyone, not only us. We again ask for you to quickly resolve this matter and further to help us in our reclassification and PMA efforts to make mobile bearing ankles available to patients in the USA so that its patients may have the same superior treatment available to the rest of the world.

Sincerely

Michael J. Pappas

Michael J. Pappas Ph.D., P.E.
President, Endotec

Cc. Les Weinstein, Tracy Forfa, Steve Ziemba

Encl.

ENDOTEC

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FACSIMILE TRANSMITTAL SHEET

TO: Jenny Butler	FROM: Jared Pappas
COMPANY: FDA – Ombudsmen's Office	DATE: 10/8/2003
FAX NUMBER: 301-827-6870	TOTAL NO. OF PAGES INCLUDING COVER: 3
PHONE NUMBER: 301-827-3390	SENDER'S REFERENCE NUMBER: Endotec Appeal
RE: Citizen's Petition	YOUR REFERENCE NUMBER:

☑ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

Dear Ms. Butler,

With reference to my recent telephone conversation with Ms. Laurie Lenkel, please find attached Sections 10:30 c and e, in order to complete a Citizen's petition filed with your department.

This appeal was originally filed in February 2002 and our Reclassification petition was filed August 2001. Therefore, having already waited years for resolution to this issue, we would appreciate an expedited review of this petition. To wait a further 6-months (180 days) would, in our opinion, be detrimental to the American public as a whole.

Thank you for your attention in this matter

Sincerely,

Jared Pappas
Endotec Inc.
jpappas@endotec.com

Environmental Impact
[As required by 21 CFR 10.30(c)]

The undersigned believes, that under 21 CFR 25.34 (b), this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

[Signature]

Michael J. Pappas, Ph.D., P. E.
[Typed name]

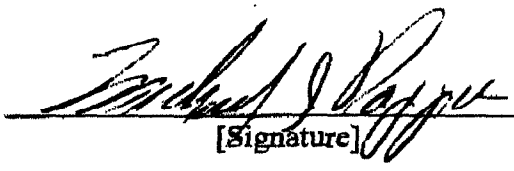
October 7, 2003
[Dated]

50 South Center Street, Unit 10, Orange NJ 07050
[Address]

973-672-3200
[Telephone]

CERTIFICATION
[As required by 21 CFR 10.30(e)]

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



[Signature]

Michael J. Pappas, Ph.D., P. E.
[Typed name]

October 7, 2003
[Dated]

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