

1

00:00:08,350 --> 00:00:09,730

I don't see an agreement.

2

00:00:11,920 --> 00:00:13,276

I don't see an agreement there.

3

00:00:13,280 --> 00:00:14,644

There's no further communication

4

00:00:14,644 --> 00:00:16,349

regarding the fact that that

5

00:00:16,349 --> 00:00:18,202

was not the caller. Us finally.

6

00:00:18,202 --> 00:00:20,519

And the reason you probably didn't get

7

00:00:20,519 --> 00:00:22,662

one is because we're they're closed,

8

00:00:22,662 --> 00:00:24,948

that the federal government is closed,

9

00:00:24,950 --> 00:00:25,829

that I understand.

10

00:00:25,829 --> 00:00:27,294

I understand these people are

11

00:00:27,294 --> 00:00:28,880

using that to their advantage,

12

00:00:28,880 --> 00:00:33,176

which I I I appreciate I get it.

13

00:00:33,180 --> 00:00:36,220

But just looking at this,

14

00:00:36,220 --> 00:00:37,540

it might take me a minute,

15

00:00:37,540 --> 00:00:39,684

but I'm gonna find if I'm gonna find

16

00:00:39,684 --> 00:00:40,960

where formulations are necessary.

17

00:00:40,960 --> 00:00:44,614

If you're considering a friend of control.

18

00:00:44,620 --> 00:00:45,310

Excuse me.

19

00:01:27,750 --> 00:01:28,090

Turn on.

20

00:01:33,700 --> 00:01:34,936

Are you planing on taping today?

21

00:01:37,720 --> 00:01:40,357

Get my computer working. OK,

22

00:01:40,357 --> 00:01:42,940

let me know when you start. Turn on.

23

00:01:58,040 --> 00:01:58,580

(b) (4) turn on.

24

00:02:03,120 --> 00:02:03,670

Start recording.

25

00:02:07,580 --> 00:02:09,956

OK. Hey, Tim. When you get a chance,

26

00:02:09,960 --> 00:02:11,622

go ahead and bring your camera

27

00:02:11,622 --> 00:02:12,890

out, please. Thank you.

28

00:02:15,920 --> 00:02:17,660

It's already set up there.

29

00:02:17,660 --> 00:02:18,530

Oh, is it already on?

30

00:02:22,340 --> 00:02:22,950

Thank you.

31

00:04:22,880 --> 00:04:25,960

As anticipated impossible to get someone,

32

00:04:25,960 --> 00:04:27,160

I called three different numbers,

33

00:04:27,160 --> 00:04:29,760

so sorry for my clarification.

34

00:04:29,760 --> 00:04:31,020

Yeah, I mean, I'm just gonna let you know.

35

00:04:31,020 --> 00:04:32,980

It's I'm not the one.

36

00:04:32,980 --> 00:04:35,196

I'm just collecting documents.

37

00:04:35,196 --> 00:04:39,510

I am a cog in this machine I'm getting documents.

38

00:04:39,510 --> 00:04:41,694

I'm only going by the 414 letter

39

00:04:41,694 --> 00:04:43,631

because I see no agreement agreement

40

00:04:43,631 --> 00:04:45,623

in that in that e-mail chain.

41

00:04:45,630 --> 00:04:47,582

I understand. There is no affirmative or or

42

00:04:47,582 --> 00:04:49,794

To say it's a refusal as inaccurate because we

43

00:04:49,794 --> 00:04:51,809

thought we had an agreement with the FDA.

44

00:04:51,810 --> 00:04:52,740

Well, you didn't.

45

00:04:52,740 --> 00:04:54,290

Well, there's there's no way.

46

00:04:54,290 --> 00:04:55,826

There's no way to verify that.

47

00:04:55,830 --> 00:04:57,142

So we're not refusing.

48

00:04:57,142 --> 00:04:59,968

We thought we were in agreement with the FDA.

49

00:04:59,970 --> 00:05:00,576

You're saying.

50

00:05:00,576 --> 00:05:01,586

Well I'm just letting you know

51

00:05:01,590 --> 00:05:03,030

You're not because there's no agreement.

52

00:05:03,030 --> 00:05:03,870

I mean, she showed me.

53

00:05:03,870 --> 00:05:05,646

She showed me the the documentation.

54

00:05:05,650 --> 00:05:06,766

There is no agreement in that.

55

00:05:06,770 --> 00:05:07,052

Well,

56

00:05:07,052 --> 00:05:09,308

we put in writing and she didn't say

57

00:05:09,308 --> 00:05:12,570

anything about that wasn't the case.

58

00:05:12,570 --> 00:05:14,070

There is nothing in writing regarding

59

00:05:14,070 --> 00:05:16,417

the fact that that was not proper or

60

00:05:16,417 --> 00:05:18,265

that that was not agreeable because we

61

00:05:18,323 --> 00:05:19,877
had the original 414 letter stating

62

00:05:19,877 --> 00:05:22,048
this is what we want. 414 letter?

63

00:05:22,048 --> 00:05:25,480
Yeah, that letter that was sent with the 482C.

64

00:05:25,480 --> 00:05:27,560
OK. Request for records...

65

00:05:27,560 --> 00:05:27,903
Understood.

66

00:05:27,903 --> 00:05:30,304
I can verify with my supervisor who

67

00:05:30,304 --> 00:05:32,244
is actually the one communicating

68

00:05:32,244 --> 00:05:33,435
with (b) (6), (b) (7)(C) (indistinguishable).

69

00:05:33,440 --> 00:05:35,240
He may have had some telephone

70

00:05:35,240 --> 00:05:37,052
conversation with (b) (6), (b) (7)(C) which I'm I'm sure,

71

00:05:37,052 --> 00:05:38,192
may have been the case.

72

00:05:38,200 --> 00:05:40,342
I can verify whether or not he

73

00:05:40,342 --> 00:05:42,590
had that oral communication and.

74

00:05:42,590 --> 00:05:42,831
That's,

75

00:05:42,831 --> 00:05:44,277
I mean that's that's not something

76

00:05:44,277 --> 00:05:46,842
I can. I understand. Rely upon.

77

00:05:46,842 --> 00:05:50,184
I understand that although we are

78

00:05:50,184 --> 00:05:52,686
under an ethical obligation not to

79

00:05:52,686 --> 00:05:55,170
misrepresent any communication. As am I.

80

00:05:55,170 --> 00:05:55,810
I mean,

81

00:05:55,810 --> 00:05:57,730
I mean I understand that and

82

00:05:57,811 --> 00:05:59,964
obviously I would assume everybody's

83

00:05:59,964 --> 00:06:01,420
telling the truth here.

84

00:06:01,420 --> 00:06:04,240
Absolutely.

85

00:06:04,240 --> 00:06:06,640
Have have you come across a

86

00:06:06,640 --> 00:06:07,840
provision where formulations,

87

00:06:07,840 --> 00:06:09,975
if they rely on .. No not specifically,

88

00:06:09,980 --> 00:06:12,242
because I'm trying to scan it such as I can..

89

00:06:12,242 --> 00:06:13,797
such as formulation lethal to the pathogen.

90

00:06:13,800 --> 00:06:15,800
Here we go hazard evaluation

91

00:06:15,800 --> 00:06:17,000
required by paragraph.

92

00:06:17,000 --> 00:06:19,502
of this section must include an evaluation

93

00:06:19,502 --> 00:06:20,753
environmental pathogens where...

94

00:06:20,760 --> 00:06:21,930
This is specific.

95

00:06:24,680 --> 00:06:26,330
It is exposed to the

96

00:06:26,330 --> 00:06:27,650
environment which is applicable.

97

00:06:27,650 --> 00:06:29,198

Prior to packaging and then the

98

00:06:29,198 --> 00:06:30,881

package animal food does not receive

99

00:06:30,881 --> 00:06:32,381

a treatment or otherwise include

100

00:06:32,381 --> 00:06:34,122

the control measures such as a

101

00:06:34,122 --> 00:06:35,447

formulation lethal to the treatment.

102

00:06:48,290 --> 00:06:51,086

That doesn't reference the recipes the

103

00:06:51,086 --> 00:06:54,075

the formulation they have provided the.

..

104

00:06:54,075 --> 00:06:57,795

The component parts as well as also.. But,

105

00:06:57,800 --> 00:06:59,540

but also you have to understand

106

00:06:59,540 --> 00:07:01,080

is when you're talking about.

107

00:07:01,080 --> 00:07:05,004

Preventive controls there are very specific

108

00:07:05,004 --> 00:07:07,320

parameters that you need to specify,

109

00:07:07,320 --> 00:07:10,440
so if they're using (b) (4).

110

00:07:10,440 --> 00:07:12,402
Or some sort of formulation thereof

111

00:07:12,402 --> 00:07:14,325
as an inhibition factor or hurdle

112

00:07:14,325 --> 00:07:16,264
step or whatever you wanna call it,

113

00:07:16,270 --> 00:07:19,084
you have to have parameters set forth

114

00:07:19,084 --> 00:07:22,068
that you're going to follow and monitor

115

00:07:22,068 --> 00:07:24,612
and document and verify and validate

116

00:07:24,620 --> 00:07:26,220
all of those things need to be done.

117

00:07:26,220 --> 00:07:28,064
Understood. Which would infer

118

00:07:28,064 --> 00:07:29,908
formulation would be provided.

119

00:07:29,910 --> 00:07:32,290
So that way we can.

120

00:07:32,290 --> 00:07:34,010
Make a scientific judgment whether

121

00:07:34,010 --> 00:07:35,386
it's working or not.

122

00:07:35,390 --> 00:07:35,642
Understood.

123

00:07:35,642 --> 00:07:37,406
Well, let me ask you this question.

124

00:07:37,410 --> 00:07:40,374
Would you be satisfied with being

125

00:07:40,374 --> 00:07:43,369
presented the full unredacted versions as,

126

00:07:43,370 --> 00:07:46,018
but being allowed to copy only the redacted

127

00:07:46,018 --> 00:07:48,100
versions for privacy considerations?

128

00:07:50,480 --> 00:07:51,888
I mean, sure, but I mean, I'm.

129

00:07:51,888 --> 00:07:53,736
I'm gonna document whatever I read.

130

00:07:53,740 --> 00:07:55,162
I'm gonna. I'm gonna put it in my book.

131

00:08:00,550 --> 00:08:01,498
Because if you don't,

132

00:08:01,498 --> 00:08:03,186
if you don't tell me, I know.

133

00:08:03,186 --> 00:08:04,922

I'm just. I'm just letting you know,

134

00:08:04,930 --> 00:08:06,309

this is this is going to be.

135

00:08:06,310 --> 00:08:08,746

This is going to be continuing issue

136

00:08:08,746 --> 00:08:11,177

because if you're using that as a

137

00:08:11,177 --> 00:08:13,547

hurdle step or an inhibition factor or

138

00:08:13,547 --> 00:08:15,850

a a means to significantly prevent or

139

00:08:15,850 --> 00:08:17,990

minimize a hazard which you are doing,

140

00:08:17,990 --> 00:08:20,930

I mean which you state you're doing,

141

00:08:20,930 --> 00:08:23,307

it has to be spelled out to us that way we

142

00:08:23,307 --> 00:08:25,316

can rely on scientific evidence that yes,

143

00:08:25,320 --> 00:08:26,590

this is going to work.

144

00:08:26,590 --> 00:08:30,268

This much (b) (4) in this product.

145

00:08:30,270 --> 00:08:31,846

Is going to work.

146

00:08:31,846 --> 00:08:34,650

Otherwise we have no scientific basis that,

147

00:08:34,650 --> 00:08:37,880

I mean you could. I don't know if I agree with that.

148

00:08:37,880 --> 00:08:38,946

There's there's. There's nothing.

149

00:08:38,946 --> 00:08:40,884

There's nothing telling us that that.

150

00:08:40,890 --> 00:08:42,010

Of course you could put.

151

00:08:42,010 --> 00:08:43,418

You could put like.

152

00:08:43,418 --> 00:08:45,515

Let's just say, let's just say

153

00:08:45,515 --> 00:08:47,653

you're making a batch of 50,000 lbs,

154

00:08:47,653 --> 00:08:50,957

or 5000 lbs if you're just putting in a

155

00:08:50,957 --> 00:08:54,796

carton full. Like of ^{(b) (4)} in the same.

156

00:08:54,800 --> 00:08:55,581

Amount.

157

00:08:55,581 --> 00:08:59,486

So now over that varying batch size,

158

00:08:59,490 --> 00:09:01,602

that's probably not going to work

159

00:09:01,602 --> 00:09:02,906

on the 50,000 lb batch.

160

00:09:02,906 --> 00:09:05,290

It might work on the 5000 pound batch,

161

00:09:05,290 --> 00:09:08,116

but that's what we that's what we have to see. The

162

00:09:08,116 --> 00:09:10,521

scientific way to determine that is to is to

163

00:09:10,521 --> 00:09:13,045

test your product for (b) (4) after the fact.

164

00:09:13,050 --> 00:09:16,628

OK which case we would if if that's

165

00:09:16,628 --> 00:09:17,758

if that's what you're saying,

166

00:09:17,760 --> 00:09:20,820

then we would require your parameters.

167

00:09:20,820 --> 00:09:21,687

That where, OK,

168

00:09:21,687 --> 00:09:24,080

where where you want your (b) (4) to fall?

169

00:09:24,080 --> 00:09:25,716

Like, quantitatively, qualitatively as

170

00:09:25,716 --> 00:09:28,470

well because you can't just use any.

171

00:09:28,470 --> 00:09:29,790

I mean, theoretically I I don't.

172

00:09:29,790 --> 00:09:30,828

I don't know enough about it,

173

00:09:30,830 --> 00:09:32,365

but something tells me you

174

00:09:32,365 --> 00:09:34,190

probably just can't use any (b) (4).

175

00:09:34,190 --> 00:09:36,476

Well, we have a processing authority

176

00:09:36,476 --> 00:09:38,880

who has set the parameters.

177

00:09:38,880 --> 00:09:41,368

And (b) (6), (b) (7)(C) said the parameters at (b) (4)

178

00:09:41,368 --> 00:09:43,459

(b) (4) whatever your pathogen would be.

179

00:09:43,460 --> 00:09:47,359

OK, provide me that process authority letter.

180

00:09:47,360 --> 00:09:49,696

(b) (6), (b) (7)(C) talked to the FDA on the phone.

181

00:09:49,700 --> 00:09:50,444
I don't.

182

00:09:50,444 --> 00:09:52,304
And phone conversations have no

183

00:09:52,304 --> 00:09:54,799
bearing on my on my on what I do.

184

00:09:54,800 --> 00:09:56,135
I need documentation.

185

00:09:56,135 --> 00:09:56,580
Well, in

186

00:09:56,580 --> 00:09:58,360
(b) (6), (b) (7)(C) letter to the FRDA

187

00:09:58,360 --> 00:10:00,210
did (b) (6), (b) (7)(C) state that?

188

00:10:00,210 --> 00:10:02,937
Um Let me check with Tim. Again with that letter.

189

00:10:02,940 --> 00:10:04,172
It has to be critical limits or we

190

00:10:04,172 --> 00:10:05,479
used to call them critical limits.

191

00:10:05,480 --> 00:10:06,776
Now they are parameters. And in HAACP

192

00:10:06,776 --> 00:10:08,679
it was critical limits.

193

00:10:08,680 --> 00:10:10,065

Now it's parameters that we

194

00:10:10,065 --> 00:10:12,039

that have to be set in stone.

195

00:10:12,040 --> 00:10:13,696

So that way when that parameter

196

00:10:13,696 --> 00:10:15,480

is not met during production,

197

00:10:15,480 --> 00:10:17,405

you know when to take a corrective

198

00:10:17,405 --> 00:10:17,955

action. Exactly.

199

00:10:17,960 --> 00:10:19,226

That's why we have the parameter.

200

00:10:19,230 --> 00:10:20,440

But that's why that documentation

201

00:10:20,440 --> 00:10:22,597

has to be done on every batch and we

202

00:10:22,597 --> 00:10:24,180

have to be able to visualize yes,

203

00:10:24,180 --> 00:10:26,358

just just as a generic number.

204

00:10:26,360 --> 00:10:29,884

Yes, we have, you know, 5000^{(b) (4)}

205

00:10:29,884 --> 00:10:32,068
Organisms in this batch because you

206

00:10:32,068 --> 00:10:34,448
know such and such person said that

207

00:10:34,448 --> 00:10:36,998
we have to have this much, you know,

208

00:10:36,998 --> 00:10:39,476
this much^{(b) (4)} per this size batch.

209

00:10:42,050 --> 00:10:45,730
The, the amount of what we add has no.

210

00:10:45,730 --> 00:10:49,090
Bearing on how much^{(b) (4)} gets in there or not.

211

00:10:49,090 --> 00:10:51,610
I mean, I I don't know that I'm.

212

00:10:51,610 --> 00:10:53,968
I'm not. I'm not that I'm not the PhD.

213

00:10:53,970 --> 00:10:55,058
I'm a document collector.

214

00:10:55,058 --> 00:10:56,418
I I collect these documents

215

00:10:56,418 --> 00:10:57,925
and I pass them to the PHD's.

216

00:10:57,930 --> 00:10:59,786
And they're the ones that make the decisions.

217

00:10:59,790 --> 00:11:02,345

I've been tasked to collect these documents.

218

00:11:02,350 --> 00:11:03,290

And you're telling me you're

219

00:11:03,290 --> 00:11:04,230

not going to provide it?

220

00:11:04,230 --> 00:11:05,170

So we're not telling

221

00:11:05,170 --> 00:11:06,580

we're not going to provide it.

222

00:11:06,580 --> 00:11:07,861

We're we're agreeing.

223

00:11:07,861 --> 00:11:10,423

to provide what we agreed

224

00:11:10,423 --> 00:11:12,409

with with the FDA to provide.

225

00:11:12,410 --> 00:11:14,050

This isn't an ongoing discussion.

226

00:11:14,050 --> 00:11:16,606

They told you what they wanted and that's it.

227

00:11:16,610 --> 00:11:18,615

Well, here's what. The the discussion

228

00:11:18,615 --> 00:11:20,219

happens after you refuse.

229

00:11:20,220 --> 00:11:21,830

Then, if you, if you choose to,

230

00:11:21,830 --> 00:11:23,048

you know, make it a legal matter,

231

00:11:23,050 --> 00:11:23,678

that's where.

232

00:11:23,678 --> 00:11:25,248

That's where folks like this,

233

00:11:25,250 --> 00:11:26,715

you know, individual here, billable

234

00:11:26,715 --> 00:11:27,887

hours comes into play.

235

00:11:27,890 --> 00:11:29,474

You know, I feel that you're

236

00:11:29,474 --> 00:11:30,770

overstepping because in the law,

237

00:11:30,770 --> 00:11:32,522

it says we do not have

238

00:11:32,522 --> 00:11:33,690

to provide recipes. Show,

239

00:11:33,690 --> 00:11:35,066

Show me what law this is because I'm,

240

00:11:35,070 --> 00:11:37,818

I'm coming right out of 507.

241

00:11:37,820 --> 00:11:38,988
That's my attorney's job.

242

00:11:43,920 --> 00:11:45,040
I mean, I understand you're

243

00:11:45,040 --> 00:11:46,844
pulling up 21 CFR, but what?

244

00:11:46,844 --> 00:11:49,127
What part of. I'm just talking

245

00:11:49,127 --> 00:11:50,981
about in general with with the

246

00:11:50,981 --> 00:11:52,725
way the HAACP or I'm sorry,

247

00:11:52,725 --> 00:11:54,510
I keep saying HAACP with

248

00:11:54,573 --> 00:11:56,218
the way the preventive controls um

249

00:11:56,220 --> 00:11:58,206
regulation you know is stated

250

00:11:58,206 --> 00:12:00,927
there may not be a spot in here

251

00:12:00,927 --> 00:12:02,913
where it says formulation is needed.

252

00:12:02,920 --> 00:12:05,811
But I guarantee if formulation is a

253

00:12:05,811 --> 00:12:07,501
preventive control, we need formulation.

254

00:12:07,501 --> 00:12:09,223
Is that your opinion or the

255

00:12:09,223 --> 00:12:10,129
opinion of the FDA? or

256

00:12:10,130 --> 00:12:12,164
That's that's come around 507 if

257

00:12:12,164 --> 00:12:14,960
you're using it as a preventive control.

258

00:12:14,960 --> 00:12:16,900
You need to provide documentation

259

00:12:16,900 --> 00:12:19,532
validation which tells me which is going

260

00:12:19,532 --> 00:12:22,505
to give me those parameters telling me yes,

261

00:12:22,505 --> 00:12:27,215
this scientific method has been proven.

262

00:12:27,220 --> 00:12:29,450
Either by peer review or

263

00:12:29,450 --> 00:12:31,998
And we provided you those documents.

264

00:12:32,000 --> 00:12:33,540
That's not apples to apples

265

00:12:33,540 --> 00:12:35,080
that that that was not,

266

00:12:35,080 --> 00:12:36,788
that was not talking about your product

267

00:12:36,788 --> 00:12:38,660
that was not talking about anything.

268

00:12:38,660 --> 00:12:39,086
I don't,

269

00:12:39,086 --> 00:12:41,090
I'm not sure I'm talking about much of any

270

00:12:41,090 --> 00:12:43,596
product except in a more general sense.

271

00:12:43,600 --> 00:12:46,864
We need something in a very specific sense.

272

00:12:46,870 --> 00:12:49,510
Specific to your process or process

273

00:12:49,510 --> 00:12:51,535
like yours where like I like I

274

00:12:51,535 --> 00:12:53,397
like I called it before an apples

275

00:12:53,397 --> 00:12:54,387
to apples comparison.

276

00:12:54,390 --> 00:12:55,797
That's what we that's what we expect,

277

00:12:55,800 --> 00:12:59,136

No, that's not the way I'm interpreting

278

00:12:59,140 --> 00:13:00,304

What they're asking for,

279

00:13:00,304 --> 00:13:01,759

they're when I read it,

280

00:13:01,760 --> 00:13:04,220

it says you have to have um

281

00:13:04,220 --> 00:13:06,008

Peer reviewed, you know,

282

00:13:06,008 --> 00:13:07,796

applicable science and that's

283

00:13:07,796 --> 00:13:09,798

there's plenty of it out there.

284

00:13:09,800 --> 00:13:10,703

We provided it,

285

00:13:10,703 --> 00:13:12,208

we provided a processing authority

286

00:13:12,208 --> 00:13:14,453

and that agreed with us. And in that

287

00:13:14,453 --> 00:13:16,129

peer reviewed article you gave me it.

288

00:13:16,130 --> 00:13:18,518

It's it lays out very specific

289

00:13:18,518 --> 00:13:20,110

(b) (4) that they use.

290

00:13:20,110 --> 00:13:22,366

Very specific speciations of these (b) (4),

291

00:13:22,370 --> 00:13:24,338

and if you're not using those

292

00:13:24,338 --> 00:13:25,940

specific speciations of that (b) (4),

293

00:13:25,940 --> 00:13:29,078

then it's not apples to apples.

294

00:13:29,080 --> 00:13:31,408

That's just that's that's just what,

295

00:13:31,410 --> 00:13:34,188

that's just what this tells you.

296

00:13:34,190 --> 00:13:36,890

I mean, I I don't know how else to say it.

297

00:13:36,890 --> 00:13:38,474

I think what I would recommend

298

00:13:38,474 --> 00:13:40,352

is before you put in your book

299

00:13:40,352 --> 00:13:42,123

that we refuse to give you these.

300

00:13:42,130 --> 00:13:44,350

Let us talk amongst ourselves.

301

00:13:44,350 --> 00:13:47,031

About maybe giving you the percentages

302

00:13:47,031 --> 00:13:49,236

because you already copied them,

303

00:13:49,240 --> 00:13:50,230

we won't make you copy them.

304

00:13:50,230 --> 00:13:51,650

We'll copy them ourselves and

305

00:13:51,650 --> 00:13:52,786

give them to you.

306

00:13:52,790 --> 00:13:54,230

But if you want to start your scanning,

307

00:13:54,230 --> 00:13:55,530

we'll discuss it. All right.

308

00:13:55,530 --> 00:13:56,646

And then we'll let you know.

309

00:13:56,650 --> 00:13:59,026

All right. Sounds good.

310

00:13:59,026 --> 00:13:59,620

Thanks.

311

00:13:59,620 --> 00:14:02,945

Do you need this additional general FDA background?

312

00:14:02,950 --> 00:14:03,239

Yeah,

313

00:14:03,239 --> 00:14:05,840

I would like to see it because I I

314

00:14:05,916 --> 00:14:09,367

I just as you can see this is FDA

315

00:14:09,367 --> 00:14:10,660

general Enforcement Regulations

316

00:14:10,743 --> 00:14:12,500

overarching for the entire.

317

00:14:17,980 --> 00:14:20,676

And you can see it references here 21

318

00:14:20,676 --> 00:14:23,369

USC and all the applicable subparts

319

00:14:23,369 --> 00:14:27,550

of the chapter including 350C 350D 350E.

320

00:14:27,550 --> 00:14:30,400

What's 350C? I can pull it up for you.

321

00:14:30,400 --> 00:14:34,288

I mean, does it mention 507 on there?

322

00:14:34,290 --> 00:14:37,207

This is. I'm referencing the

323

00:14:37,207 --> 00:14:39,302

statutory authority here and the

324

00:14:39,302 --> 00:14:41,120

statute statutes are references.

325

00:14:41,120 --> 00:14:42,830
Ohh, this is USC. Not OK.

326

00:14:42,830 --> 00:14:44,380
These are the enabling statutes,

327

00:14:44,380 --> 00:14:47,903
and I believe we are in the 350C 350D

328

00:14:47,903 --> 00:14:49,918
because that's regarding adulterated food.

329

00:14:49,920 --> 00:14:50,770
OK, let's check it out.

330

00:14:50,770 --> 00:14:52,730
I mean, I don't know what it says.

331

00:14:52,730 --> 00:14:54,319
I'm not sure if this PDF will

332

00:14:54,319 --> 00:14:55,719
let me link right to it.

333

00:14:58,270 --> 00:14:58,960
Maybe it will.

334

00:15:03,460 --> 00:15:05,008
Like I said, I mean, it's not like

335

00:15:05,008 --> 00:15:06,288
my interpretation is gonna make

336

00:15:06,288 --> 00:15:08,417
or break this because it's not my

337

00:15:08,417 --> 00:15:09,554
interpretation that matters. Certainly.

338

00:15:09,554 --> 00:15:10,718
I mean, we all understand that,

339

00:15:10,720 --> 00:15:11,670
right? Certainly.

340

00:15:14,490 --> 00:15:15,460
Adulterated food.

341

00:15:19,310 --> 00:15:21,326
And as you know, the definition for

342

00:15:21,326 --> 00:15:23,307
food under 21 USC food and feed.

343

00:15:31,810 --> 00:15:33,546
OK. So I mean, what's it telling me?

344

00:15:33,550 --> 00:15:37,270
I mean, where's where's the smoking gun here?

345

00:15:37,270 --> 00:15:39,436
Regulations promulgated under

346

00:15:39,436 --> 00:15:41,760
350 state, where is it saying

347

00:15:41,760 --> 00:15:42,860
formulation isn't part of it?

348

00:15:47,860 --> 00:15:50,198
The records that are excluded from the

349

00:15:50,198 --> 00:15:52,313

subpart which is promulgated directly

350

00:15:52,313 --> 00:15:54,468

under 350C regarding adulterated food.

351

00:16:01,100 --> 00:16:03,698

I understand that the interpretation and um

352

00:16:05,960 --> 00:16:09,150

Where's formulation there? Recipe.

353

00:16:12,080 --> 00:16:14,145

I can pull up the definition of

354

00:16:14,145 --> 00:16:15,748

recipe if you'd like that as well.

355

00:16:19,250 --> 00:16:23,074

Something tells me that that is an outdated.

356

00:16:23,080 --> 00:16:24,874

Current regulation current

357

00:16:24,874 --> 00:16:27,282

through January 17 2019,

358

00:16:27,282 --> 00:16:30,530

I understand that is 5 days ago. However,

359

00:16:30,530 --> 00:16:33,890

(b) (4) and you can believe me or not,

360

00:16:33,890 --> 00:16:36,445

but (b) (4) is updated on a daily

361

00:16:36,445 --> 00:16:38,900
basis with a new regulations.

362

00:16:38,900 --> 00:16:41,612
Like I said, this was written at a

363

00:16:41,612 --> 00:16:44,228
time when before 507 even existed.

364

00:16:44,230 --> 00:16:46,378
I don't know what supersedes what.

365

00:16:46,380 --> 00:16:49,334
I don't know. I'm not the lawyer.

366

00:16:49,334 --> 00:16:51,690
I don't know if 507 supersedes that.

367

00:16:51,690 --> 00:16:53,930
I have no idea, so I can't.

368

00:16:53,930 --> 00:16:55,955
I mean that is not something I was ever

369

00:16:55,955 --> 00:16:57,705
presented with in any of my training ever.

370

00:16:57,710 --> 00:16:58,462
So anywhere.

371

00:16:58,462 --> 00:17:00,342
Wouldn't your lawyers have expressed

372

00:17:00,342 --> 00:17:02,849
that to us if that was the case?

373

00:17:02,850 --> 00:17:04,026

I don't know what they expressed.

374

00:17:04,030 --> 00:17:05,302

I have no idea why you saw what

375

00:17:05,302 --> 00:17:07,360

they wrote to us, so they didn't.

376

00:17:07,360 --> 00:17:09,810

They didn't say anything exactly.

377

00:17:09,810 --> 00:17:11,854

After we told them that we weren't

378

00:17:11,854 --> 00:17:13,540

going to provide the formulas.

379

00:17:13,540 --> 00:17:15,178

I I don't know. I can't speak for them.

380

00:17:15,180 --> 00:17:15,980

I can't think for them.

381

00:17:15,980 --> 00:17:16,740

I have no idea.

382

00:17:16,740 --> 00:17:17,806

I wish I could. I wish.

383

00:17:17,806 --> 00:17:18,877

I wish we could call them right

384

00:17:18,877 --> 00:17:19,916

now and figure this all out.

385

00:17:19,920 --> 00:17:23,334

But it's not just the conditions under

386

00:17:23,334 --> 00:17:25,818

which we are operating are extreme.

387

00:17:25,820 --> 00:17:28,856

Obviously, we don't have, you know,

388

00:17:28,860 --> 00:17:31,260

90% of the people that we need to talk to.

389

00:17:31,260 --> 00:17:33,020

So I mean, either we're at an impasse

390

00:17:33,020 --> 00:17:34,956

or you guys are going to discuss it,

391

00:17:34,960 --> 00:17:36,340

I don't know, but I can't.

392

00:17:36,340 --> 00:17:40,050

I can't go by that regulation because.

393

00:17:40,050 --> 00:17:41,026

That regulation.

394

00:17:41,026 --> 00:17:42,490

In my mind,

395

00:17:42,490 --> 00:17:43,742

supersedes that regulation because

396

00:17:43,742 --> 00:17:46,050

you're using it as a preventive control.

397

00:17:46,050 --> 00:17:46,259

Now,

398

00:17:46,259 --> 00:17:47,304

you you've mentioned a couple

399

00:17:47,304 --> 00:17:48,400

of times in my mind,

400

00:17:48,400 --> 00:17:50,008

the way I'm interpreting it right,

401

00:17:50,010 --> 00:17:50,511

understandably,

402

00:17:50,511 --> 00:17:53,517

we have some differences on that

403

00:17:53,517 --> 00:17:55,899

interpretation between listen and your

404

00:17:55,899 --> 00:17:57,114

interpretations are representative

405

00:17:57,114 --> 00:18:00,337

of the FDA and you are stating that

406

00:18:00,337 --> 00:18:02,605

you are just collecting the records.

407

00:18:02,610 --> 00:18:04,773

Would you be satisfied in this case

408

00:18:04,773 --> 00:18:07,213

if we present to you the records that

409

00:18:07,213 --> 00:18:09,420
we believe and if your scientific,

410

00:18:09,420 --> 00:18:10,962
the people you present all your

411

00:18:10,962 --> 00:18:12,560
records to are not satisfied,

412

00:18:12,560 --> 00:18:14,070
then we'll have that conversation

413

00:18:14,070 --> 00:18:14,976
about the percentages.

414

00:18:14,980 --> 00:18:16,060
Like I said, present me,

415

00:18:16,060 --> 00:18:18,172
present me present to me or

416

00:18:18,172 --> 00:18:20,260
present me with whatever you will.

417

00:18:20,260 --> 00:18:21,748
I just have to go back to them

418

00:18:21,748 --> 00:18:23,361
and tell them what you were or

419

00:18:23,361 --> 00:18:24,551
were not willing to provide.

420

00:18:24,560 --> 00:18:24,938
I mean that's.

421

00:18:24,938 --> 00:18:26,436

I mean, that's just how it's going to roll.

422

00:18:26,440 --> 00:18:28,876

I mean, I'm good with that.

423

00:18:28,880 --> 00:18:30,878

No one can address it with the people that

424

00:18:30,878 --> 00:18:32,498

actually have a decision making ability,

425

00:18:32,500 --> 00:18:32,790

right?

426

00:18:32,790 --> 00:18:33,080

Absolutely.

427

00:18:33,080 --> 00:18:33,370

Right.

428

00:18:33,370 --> 00:18:35,400

Yeah, if if they're not happy with

429

00:18:35,449 --> 00:18:36,897

not providing the percentages.

430

00:18:36,900 --> 00:18:39,679

And I believe you provide the validation

431

00:18:39,679 --> 00:18:42,699

method rather than the front end percentages.

432

00:18:42,700 --> 00:18:44,458

So if they want the percentages

433

00:18:44,458 --> 00:18:45,955
as well as boots and suspenders,

434

00:18:45,955 --> 00:18:48,555
then we'll we'll go right at that point.

435

00:18:48,560 --> 00:18:48,990
Now,

436

00:18:48,990 --> 00:18:52,000
what validation method are we talking about?

437

00:18:52,000 --> 00:18:53,992
Copy that part. Yeah.

438

00:18:53,992 --> 00:18:55,262
OK, OK, because that's important.

439

00:18:55,262 --> 00:18:56,364
I mean, that's production record.

440

00:18:56,364 --> 00:18:56,840
I mean,

441

00:18:56,840 --> 00:18:58,884
that's what we see as production record.

442

00:18:58,890 --> 00:19:00,090
#3. We haven't gotten there.

443

00:19:00,090 --> 00:19:01,042
OK, alright, that's fine.

444

00:19:01,042 --> 00:19:03,150
I just that was something else that I was

445

00:19:03,150 --> 00:19:04,810

thinking about last night that I wanted to.

446

00:19:04,810 --> 00:19:06,245

I wanted to bring up as well

447

00:19:06,245 --> 00:19:07,860

that that in production records

448

00:19:07,860 --> 00:19:09,328

include monitoring, verification,

449

00:19:09,328 --> 00:19:11,400

validation, all that stuff.

450

00:19:11,400 --> 00:19:14,020

Those are all production records.

451

00:19:14,020 --> 00:19:15,504

Because you're monitoring production,

452

00:19:15,504 --> 00:19:16,617

you're verifying production.

453

00:19:16,620 --> 00:19:18,128

You're validating production methods.

454

00:19:20,920 --> 00:19:23,320

I'm I'm Just that's that's that's how FDA sees it.

455

00:19:23,320 --> 00:19:25,340

So I just wanted to bring that up as well.

456

00:19:25,340 --> 00:19:26,988

Now one thing I did want to address

457

00:19:26,988 --> 00:19:28,654
before we get into it today is a

458

00:19:28,654 --> 00:19:30,163
lot of the production records are

459

00:19:30,163 --> 00:19:32,090
specifically pertaining to (b) (4), the

460

00:19:32,090 --> 00:19:34,120
instructions that they give to (b) (4).

461

00:19:34,120 --> 00:19:35,863
I believe they have presented you with

462

00:19:35,863 --> 00:19:37,577
or are prepared to present you with,

463

00:19:37,580 --> 00:19:39,536
but certain records that pertain to

464

00:19:39,536 --> 00:19:41,469
the actual production of (b) (4) are

465

00:19:41,469 --> 00:19:43,179
not under the control of listeners.

466

00:19:43,180 --> 00:19:45,574
The third party contact plan where

467

00:19:45,574 --> 00:19:47,492
I believe we're happy to work with

468

00:19:47,492 --> 00:19:49,330
you to obtain those records.

469

00:19:49,330 --> 00:19:51,112

But they're not under our control

470

00:19:51,112 --> 00:19:52,003

at this point.

471

00:19:52,010 --> 00:19:53,960

I mean, they could have been.

472

00:19:53,960 --> 00:19:55,720

They they're not Lystyn records.

473

00:19:55,720 --> 00:19:56,908

They are (b) (4) .

474

00:19:59,740 --> 00:20:02,008

Wait, what we all understand is. Don't put thoughts in my mind.

475

00:20:02,010 --> 00:20:04,074

These folks control their

476

00:20:04,074 --> 00:20:06,138

production at (b) (4) .

477

00:20:06,140 --> 00:20:09,123

They ensure great degree so, so, so today.

478

00:20:09,123 --> 00:20:10,810

So so to say they they don't

479

00:20:10,872 --> 00:20:12,537

have access to those records.

480

00:20:12,540 --> 00:20:14,004

They just means they didn't ask for them.

481

00:20:14,010 --> 00:20:17,069

They instruct how to produce the records.

482

00:20:17,070 --> 00:20:20,899

As far as validation, what actually happens.

483

00:20:20,900 --> 00:20:22,330

There are (b) (4) records.

484

00:20:22,330 --> 00:20:24,172

They have a unique food facility

485

00:20:24,172 --> 00:20:25,119

registration. They have unique.

486

00:20:25,119 --> 00:20:26,078

I get it. I understand.

487

00:20:26,078 --> 00:20:27,480

You don't have to explain all that to me.

488

00:20:27,480 --> 00:20:27,964

I understand.

489

00:20:27,964 --> 00:20:29,174

I understand what you're saying.

490

00:20:29,180 --> 00:20:32,379

And by I guess legally or I

491

00:20:32,379 --> 00:20:35,821

can't call you not providing. A.

492

00:20:35,821 --> 00:20:38,407

You know another entities records a refusal.

493

00:20:38,410 --> 00:20:39,196

I understand it.

494

00:20:39,196 --> 00:20:41,380

But if you wanted them you could get them.

495

00:20:41,380 --> 00:20:42,675

I mean, if you really wanted them,

496

00:20:42,680 --> 00:20:44,440

you could get them.

497

00:20:44,440 --> 00:20:45,188

Same thing. Everything else.

498

00:20:45,188 --> 00:20:47,248

If you wanted them, you could get them.

499

00:20:47,248 --> 00:20:48,883

So that's just your opinion,

500

00:20:48,890 --> 00:20:49,410

not ours.

501

00:20:49,410 --> 00:20:52,095

OK, so I think mine is based in fact. I

502

00:20:52,095 --> 00:20:54,685

kind of in that vein if you wanted to

503

00:20:54,685 --> 00:20:57,025

inspect the records of those facilities,

504

00:20:57,030 --> 00:20:58,386

you could certainly ask to inspect

505

00:20:58,386 --> 00:20:59,790
the records of those facilities.

506

00:20:59,790 --> 00:21:01,450
I think of those facilities,

507

00:21:01,450 --> 00:21:03,434
yeah, I mean and and I I wasn't

508

00:21:03,434 --> 00:21:05,150
part of those inspections,

509

00:21:05,150 --> 00:21:06,535
I don't even those inspections

510

00:21:06,535 --> 00:21:07,643
Those inspections may still be ongoing.

511

00:21:07,650 --> 00:21:11,043
I have no idea, I think (b) (4) is. Understood

512

00:21:11,050 --> 00:21:15,388
So I mean those those things may come up.

513

00:21:15,390 --> 00:21:17,541
But I mean, I just find it strange you

514

00:21:17,541 --> 00:21:19,730
can get some records from (b) (4) ,

515

00:21:19,730 --> 00:21:22,355
but not other records from (b) (4) .

516

00:21:22,360 --> 00:21:24,100
Because like supposedly,

517

00:21:24,100 --> 00:21:27,000
(b) (6), (b) (7)(
provided me with records.

518

00:21:27,000 --> 00:21:29,130
Umm.

519

00:21:29,130 --> 00:21:31,740
Of their instructions to (b) (4) .

520

00:21:31,740 --> 00:21:33,556
It's not just instructions,

521

00:21:33,556 --> 00:21:34,918
it's documenting what's

522

00:21:34,918 --> 00:21:37,100
going on during production.

523

00:21:37,100 --> 00:21:37,417
OK?

524

00:21:37,417 --> 00:21:38,368
At (b) (4) ,

525

00:21:38,368 --> 00:21:39,636
it wasn't just instructions.

526

00:21:39,640 --> 00:21:40,084
It was.

527

00:21:40,084 --> 00:21:41,860
This is what we we this is what

528

00:21:41,926 --> 00:21:43,638
we observed during production.

529

00:21:43,640 --> 00:21:45,940
Before or after production of

530

00:21:45,940 --> 00:21:47,757
this product at (b) (4) .

531

00:21:47,757 --> 00:21:48,056
Understood.

532

00:21:48,056 --> 00:21:49,551
Then maybe they've gone above

533

00:21:49,551 --> 00:21:51,062
and beyond what they're required

534

00:21:51,062 --> 00:21:52,796
to provide you with from this

535

00:21:52,852 --> 00:21:54,250
facilities inspection. Maybe.

536

00:21:57,040 --> 00:21:58,894
So yeah, you guys can hash

537

00:21:58,894 --> 00:22:00,130
out that formulation thing.

538

00:22:00,130 --> 00:22:02,478
I'm gonna get started.

539

00:22:02,480 --> 00:22:05,160
Can I go ahead and use that bench again.

540

00:22:05,160 --> 00:22:06,136
All of my things.

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541

00:22:06,136 --> 00:22:07,718

Yeah. Yeah. Thank you.

542

00:22:23,630 --> 00:22:23,790

(b) (4) Turn off.