

901:3-17-04

**Modifications.**

Pursuant to rule 901:3-17-01 of the Administrative Code, the following sections of the 21 C.F.R. 117 are amended to read as follows:

(A) 21 C.F.R. 117.5(a) delete existing language and insert:

"Subparts C and G of this part do not apply to a qualified facility unless the FDA has withdrawn the qualified facility exemption. Qualified facilities are subject to the modified requirements in 21 C.F.R. part 117.201."

(B) 21 C.F.R. 117.201 is amended to add the following language:

"(g) Ohio department of agriculture. All records required by this part must be made promptly available to a duly authorized representative of the director of the Ohio department of agriculture for official review and copying upon oral or written request."

(C) 21 C.F.R. 117.251 delete existing language and insert:

"The process and procedure for the withdrawal of a qualified exemption will be handled and administered by the Food and Drug Administration."

(D) 21 C.F.R. 117.320 delete existing language and insert:

"All records required by this part must be made promptly available to a duly authorized representative of the director of the Ohio department of agriculture for official review and copying upon oral or written request."

(E) 21 C.F.R. 117.325 delete existing language and insert:

"Records obtained by the Ohio department of agriculture in accordance with this part are subject to disclosure pursuant to chapter 149 of the Ohio Revised Code."

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

Promulgated Under:	119.03
Statutory Authority:	3715.02, 3715.021
Rule Amplifies:	3715.59, 3715.60, 3715.62