Ohio Administrative Code

Rule 901:11-3-09 Modifications - good manufacturing practice, hazard analysis and risk-based preventive controls for human food.

Effective: October 31, 2024

Pursuant to rule 901:11-3-06 of the AdministrativeCode, the following sections of the 21 C.F.R. 117 shall be amended to read asfollows:

(A) 21 C.F.R. 117.5(a) will read as:

"Subparts C and G of this part do not apply to a qualified facility unless the FDA has withdrawn the qualified facility exemption.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 will read as:

"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 will read as:

"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 will read as:

"Records obtained by the Ohio department of agriculture in accordance with this part are subject to disclosure pursuant to Chapter 149. of the Revised Code and section 917.17 of the Revised Code."