DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715 Industry Information: www.fda.gov/oc/industry	29 May - 1 June, 2017
	FEI NUMBER 3006348106

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Paolo Avaltroni, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Gallini S.r.L.	Via San Faustino,88
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
41037 Mirandola (MO), Italy	Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

The observations noted in this Form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

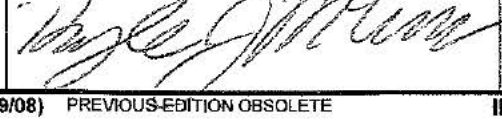
Observation 1

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures. Specifically, multiple processes which require validation according to your Process Validation Procedure (b) (4) and Validation Master Plan, (b) (4), have validations which are inadequate:

(b) (4) requires (b) (4) for the (b) (4) which was (b) (4)

- Validation Report, (b) (4), did not perform a test to measure the actual (b) (4) (b) (4). A (b) (4) was performed but did not measure the strength of the (b) (4). The manufacturing procedure, (b) (4), used for the validation does not indicate (b) (4) for the (b) (4) which is a critical parameter. The processing parameters for (b) (4) were not stated on the batch record for the lots produced for this validation. The sample size indicated for each validation run was (b) (4) units, however, only (b) (4) units were tested per batch. The (b) (4) batches produced for this validation consisted of (b) (4) units each and were not randomly selected from a total lot. The (b) (4) parameter for (b) (4) was not evaluated within the validation protocol or report. In addition, the (b) (4) was cleared in (b) (4) 1996 and this was the first validation report for (b) (4) and was released Jan 11, 2016.

- Validation Report, (b) (4), did not perform a test to measure the actual (b) (4) (b) (4). A (b) (4) was performed but did not measure the strength of the (b) (4). (b) (4) (b) (4), and amount of (b) (4) were identified as critical parameters but were not all analyzed for minimum and maximum processing parameters. These parameters are not clearly defined within the manufacturing procedure (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Kyle J. McCracken, CSO	1 June 2017

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- Packaging Validation for (b) (4) (Test Report (b) (4)): There is no protocol, sample size rationale, worst product/package evaluation, operational qualification, performance qualification, and batch records for test batches could not be located.

- (b) (4) Validation (Test Report (b) (4)): There is no protocol, sample size rationale, worst product/ package evaluation, operational qualification, performance qualification, and batch records for test batches could not be located. This report includes the use of (b) (4) in which the processing parameters are not defined or evaluated.

Observation 2

Procedures for corrective and preventive action have not been adequately established. Specifically, actions were taken in response to complaints for (b) (4) as early as 30 March 2016, but CAPA (b) (4) was not initiated until 14 November 2016.

Observation 3

Procedures have not been adequately established to control product that does not conform to specified requirements. Specifically, products which fail to conform to specification are recorded within the DHR but are not evaluated, investigated, or statistically analyzed as a quality data source.

Observation 4

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been adequately established. Specifically, validated processes such as (b) (4) (b) (4) have processing parameters/settings which are not defined within their respective procedures.

Observation 5

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		Kyle J. McCracken, CSO	1 Jun 2017

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Procedures for design change have not been adequately established. Specifically, your design controls procedure, (b) (4) requires design changes to be evaluated. A change in the design for the (b) (4) (b) (4) was was from (b) (4) the (b) (4) to (b) (4). This design change had no change impact assessment as required by your procedure to ensure the change did not adversely affect the safety, efficacy, or performance specifications of the product.

Observation 6

Rework and reevaluation activities have not been documented in the device history record. Specifically, employees were observed reworking products within the (b) (4) operation but this information was not recorded on the DHR.

Observation 7

Documents were not available at all locations for which they are designated, used, or otherwise necessary. Specifically, during the inspection multiple manufacturing procedures were not available to operators in the manufacturing area.

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		Kyle J. McCoachy CSO	1 Jun 2017