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National Agency of Sanitary Surveillance - ANVISA
Health Product Technology General Management - GGTPS
Materials Technology for Health-Use Management - GEMAT
TECHNICAL NOTE # 001/2013 / GEMAT / GGTPS / ANVISA

Subject: Health products labeling Information

1. There has been increasing demand for questions about the correct interpretation of single-use product labels available on the market.

2. For a better understanding of this subject, it's necessary to clarify some definitions:

a. The term "re-sterilization" must be understood as a sterilization process of already sterilized and unused items (Inter-ministerial Ordinance MS/TEM #482/99). It should be used solely when there is some doubt about the safety of the process or the result of the initial sterilization. It cannot be used as a process which changes the expire date of a sterilized article and not used within the period defined by the manufacturer (Law #6360/76 art. 67, section IV).

b. The term "reprocessing" or, more recently, "processing" must be understood as a set of actions related to the pre-cleaning, reception, cleaning, drying, integrity and functionality evaluation, preparation, disinfection or sterilization, storage and distribution for consumer units (ANVISA RDC #15/12).

c. The term "single use product", defined by ANVISA RDC #185/2001, must be understood as any medical product intended to be used in the prevention, diagnosis, therapy, rehabilitation or contraception, usable only once, as specified by the manufacturer.

3. Before ANVISA RDC #156/06 publication, products that were considered prohibited from being reprocessed must be labeled "SINGLE USE PRODUCT" on the label.

4. With the ANVISA RDC #156/06 publication, the labels for the products in the reprocessed prohibited products list in ANVISA RE #2605/06 and those in which the manufacturer indicates that it is impossible to guarantee the safety of the product in its processing must contain on the label the words "PROHIBITED REPROCESS".

5. According to Article 8 of the ANVISA RDC #156/06 "The reprocessing of products is prohibited throughout the national territory, by any type of company or health service, from the public or private sector, when:

A. I - If they fit in item I of article 4 of this Resolution, with the words "Prohibited Reprocessing" on the label.

B. II – If they're fit in the Specific Resolution RE / ANVISA, which contains the list of prohibited products to be reprocessed.

6. Article 10 of the ANVISA RDC specifies that "The companies and health services that perform the reprocessing must adopt protocols that comply with the guidelines indicated in Specific Resolution RE / ANVISA. These guidelines are established in ANVISA RE #2606/06.

7. Article 14 established a period of three hundred and sixty-five days for manufacturers and importers to comply the Articles 6 and 7 requirements, which it's related to the products labeling specifically.

8. O Banco de Dados da Anvisa para pesquisa de rotulagem e instrução de uso é alimentado no momento do registro do produto e quando ocorre uma alteração que implique na mudança de rotulagem ou instrução de uso relacionada ao processamento do produto. The ANVISA Database for labeling research and usage instruction is fed at the time of product registration and when occurs any change that implies to some labeling or instruction of use modification related to the product processing.

9. To clarify the correct interpretation to be given to the labels content of the that are on the market we explain:

a. Products bearing on their labels, their packaging or in their instructions for use only the terms SINGLE USE or SINGLE USE PRODUCT are not in compliance with RDC #156/06, since the time limit for changing the labels already expired for, at least, five years;

b. The words "DO NOT RE-STERILIZE" should not be considered since this procedure is prohibited according to Law #6360/76;

c. Whenever the label reads "PROHIBITED REPROCESSING", regardless of any other information on the label, this product must not be processed after use.

d. The words "MANUFACTURER RECOMMENDS SINGLE USE" is unique to products considered able to process and may not be accompanied by phrases such as "DISCARD AFTER USE" or "DESTROY AFTER USE", which direct use as the single use.

10. The ANVISA RDC #156/06 did not require manufacturers and importers to formally notify ANVISA about the compliance of Article 14. The information is included in the ANVISA database as the processes are analyzed at the time of registry renewal.

11. For this reason, it is possible the occurrence of divergence in the information of the labeling content when searched in the ANVISA's electronic address, compared to the label affixed in the product that is already in the market. In such cases, the label information must always be considered, since all criteria in item 9 of this Technical Note have been met.

12. In the event of labeling as described in item 9, letter "a", the occurrence must be informed to the local Sanitary Surveillance for the adoption of the pertinent measures.

Brasília, October 3, 2013.
Materials Technology for Health-Use Management
GEMAT/GGTPS/ANVISA

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