NATIONAL ADMINISTRATIVE REGISTER · SEPTEMBER 5, 2012

REITERATION ON THE POLICY ON CONFIDENTIALITY OF INFORMATION

FDA CIRCULAR NO. 2012-013, September 05, 2012

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DIRECTIVE

The Food and Drug Administration is a regulatory body (tasked to issue licenses to establishments and registrations to products and other authorizations under its jurisdiction. It is authorized to assume primary jurisdiction in the collection of samples of health products; analyze, inspect and conduct appropriate tests on all applicable health products prior to the issuance of appropriate authorizations to ensure safety, quality and efficacy of such products made available to the consuming public. As such, it is inherent that this Office becomes the repository of documents in the performance of its regulatory, quasi-legislative and quasi-judicial function.

Thus, as public officers or agents of this Office, everyone concerned shall act at all times with high degree or prudence and propriety so as to avoid any conduct that may intentionally or unintentionally result in undermining public's faith and confidence in this institution. It is for this reason that the prohibition on Paragraph (f), Section 11 of Republic Act No, 3720, as amended by Republic Act No. 9711 is reiterated providing that:

> Section 11. The following Acts and the causing thereof are prohibited:
>
> xxx xxx xxxx
>
> (f) The using by any person to his own advantage, or revealing, other than to the Secretary or officers and employees of the Department or to the courts when relevant in any judicial proceeding under this Act, any information concerning any method or process which as a trade secret is entitled to protection."

Thus, the provisions of Administrative Order 2009-004 are likewise stressed and every employee, in whatever capacity she or he is engaged by this Office including those hired as consultant or otherwise is hereby enjoined:

a. Not to use or divulge any confidential or classified information that has come to their knowledge in the course of or by reason of their employment or engagement with this Office to further their private interests or give undue advantage to anyone or to prejudice the public interest. This prohibition shall apply even after separation of employment or engagement with the FDA. These confidential or classified information shall include but not limited to:

- Documents submitted as a requirement of licensing of establishment or registration of a product or other authorizations pertaining to method or process which as a trade secret is entitled to protection;

- Documents and papers pertaining to such official acts, transactions and decisions, determined by the President of the Republic of the Philippines or his/her duly authorized official as "Classified Information", when the reproduction or revelation of the information thereof will create a clear, and post danger to the security of the state;

- Documents, records and papers compiled for internal and external defenses and law enforcement purposes, when

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the reproduction or revelation of information thereof would:

1. Deprive a person of the right to a fair trial or an impartial adjudication;
2. Constitute an unwarranted invasion of personal privacy:
3. Endanger the life or physical safety of law enforcement and military personnel or their immediate families:

- Those which are exempted by law in addition to those provided in this section.

b. Not to alter, falsify, conceal, destroy or mutilate public records which have come into their possession in the course of, or by reason of their employment or engagement.

To implement the above, all employee or person engage by this Office as consultant or otherwise are required to sign a confidentiality undertaking (Annex I) regarding confidentiality.

Any violation of the provision of this Circular shall be dealt with accordingly. This Circular shall take effect immediately.

(SGD.) NICOLAS B. LUTERO III, Esq., CESO III
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