

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



The Supreme Court upholds the constitutionality of "FDA's search and seizure authority; FDA's power to issue cease and desist orders *motu* proprio; and the Director General's authority to padlock erring establishments"

"The protection of the public, especially children, from impure or hazardous substances is a primordial governmental concern. Undoubtedly, the FDA Act, as amended was enacted in the exercise of the police power of the State in order to promote and preserve public health and safety."

"The grant of authority to the FDA Director-General necessarily includes all such powers, even those not expressly stated, that are necessary to effectuate such authority."

-Supreme Court in the case Venus Commercial Co., Inc. vs. DOH and FDA (G.R. No. 240764; November 18, 2021)

In *Venus Commercial Co. Inc., vs. Department of Health and Food and Drug Administration* the then FDA Acting Director-General issued FDA Personnel No. 2014-220 on May 28, 2014, authorizing the FDA inspectors to enter Venus Commercial factory (Venus) to conduct an inspection, seize its violative Artex Fine Watercolor product and to padlock the said establishment after the FDA verified, through laboratory analysis, that the product contains very high amount of the toxic substance lead. It was likewise found that Venus manufactured its watercolor product without the appropriate License to Operate (LTO) issued by the FDA and the subject product is not registered with the FDA.

Venus filed a petition that sought to declare as unconstitutional Section 30 (4) of Republic Act (RA) No. 3720, as amended by RA No. 9711, and Section 2 (b) paragraph (5), Article III, Book I of Department Circular No. 2011-0101 [Implementing Rules and Regulation (IRR)] for allegedly violating its constitutional right against illegal search and seizure, as well as the constitutional command that searches and seizures be covered by judicial warrants or orders. Venus also assailed Section 10 (ff) of the amended law, for being supposedly an undue delegation of legislative power. Finally, Venus sought to invalidate FDA Personnel Order 2014-220 for purportedly violating its right to due process.

The trial court ruled in favor of Venus and declared the impugned FDA Personnel Order void. The FDA and DOH filed an appeal with the Court of Appeals which reversed the lower court's ruling.

In its Supreme Court petition, aggrieved Venus prays that the dispositions of the Court of Appeals be reversed and set aside. Venus raised the same issues and assailed for the first time the constitutionality of Section 12 (a) of RA No. 3720, as amended.

Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines

Trunk Line +63 2 857 1900

Website: www.fda.gov.ph

Fax +63 2 807 0751 Email : info@fda.gov.ph





Sections 12(a) and Section 30(4) of the law, as well as Section 2(b) paragraph (5), Article III of Department Circular No. 2011-0101 does not violate the Constitutional proscription against unreasonable searches and seizures

The Supreme Court ruled that Sections 12 (a) and Section 30 (4) of RA No. 3720, as amended, as well as Section 2 (b) paragraph (5), Article III, Book I of the IRR does not violate the Constitutional proscription against unreasonable searches and seizures. Granted that the issuance of warrant must be premised on a finding of probable cause, this rule, though admits of exceptional instances when warrantless seizures are considered permissible, one of which is the "searches incident of inspection, supervision, and regulation sanctioned by the State in the exercise of its police power. They are better known as administrative searches."

Police power is the power of the State to promote public welfare by restraining and regulating the use of liberty and property. The "power to "regulate" means the power to protect, foster, promote, preserve, and control, with due regard for the interests, first and foremost, of the public, then of the utility and its patrons." The proper exercise of police power requires the concurrence of a lawful subject and lawful method.

With respect to the **lawful subject**, the Court stressed that "Sections 12(a) and 30(4) of RA No. 3720, as amended, as well Section 2(b) paragraph (5), Article III, Book I of the IRR are clearly designed to protect the health and safety of the people against exposure to and use of hazardous products. Furthermore, FDA Personnel Order No. 2014-220 was specifically issued to prevent Venus from selling toxic watercolors to protect the public, especially young children from the risks of ingesting the same or from coming in contact with the toxic high lead component of the product. There is no question that public health was the lawful subject of the police power legislation."

On the matter of the **lawfulness of the method** applied, "xxx, the Court finds that the means employed by the legislature to protect public health and safety against the production and sale of hazardous products in the market are not only necessary but reasonable and fair. The administrative search ordered by the Director-General under the FDA Personnel Order No. 2014-220, therefore, is fair and reasonable especially since Venus did not even have a License to Operate as a manufacturer of household urban hazardous materials; and most important, the subject watercolor is not FDA registered. Indubitably, FDA Personnel Order No. 2014-220 was issued to ensure public safety under the exercise of FDA's regulatory authority."

Searches and seizures are ordinarily unreasonable without individualized suspicion of wrongdoing. However, because administrative searches primarily ensure public safety instead of detecting criminal wrongdoing, they do not require individual suspicion. Where the risk to public safety is substantial and real, blanket suspicionless searches calibrated to the risk may rank as "reasonable."

The FDA's power to issue Cease and Desist Orders Motu Proprio is Upheld

The Supreme Court observed that Venus never raised the constitutionality of Section 4(j) of RA 3720, as amended by RA 9711, granting the FDA the power to issue cease and desist orders *motu proprio* or upon verified complaint for health products, whether or not registered with the FDA. xxx xxx.

The Court ruled in this wise: "Even then, should we sustain the assailed provisions Sections 10(ff), 12(a), and 30(4) of the amended law, the power of FDA to issue cease and desist orders motu proprio under the last sentence of Section 4(j) will be deemed upheld, too. Conversely, should we declare the aforesaid provisions unconstitutional, Section 4(j) will have to fall, too, as a necessary consequence. In both instances, we proceed from the fact that all three (3) provisions are closely intertwined with, and inseparable from, Section 4(j)."

There was no undue delegation of legislative power

The Supreme Court ruled that there is no undue delegation of legislative power in this case. "Whether the final sentence of Section 10(ff) gave the FDA unbridled authority to determine what constitutes a health product, hence, void, is wholly immaterial here. Just the same, the petitioner's Artex Fine Watercolors would still be classified as "health products" within the regulatory jurisdiction of the FDA. To be sure, the petitioner's Artex Fine Watercolors squarely falls under "household/urban hazardous substances" as defined in Section 10(gg) of RA 3720 as amended."

The Director-General is authorized to padlock erring establishments

The Court in its decision concluded that "True, there is no express provision in RA 3720, as amended, authorizing the FDA Director-General to padlock a production facility pending hearing before the FDA. This authority, however, is deemed subsumed in the statutory power of the FDA-Director General "to issue orders of seizure, to seize and hold in custody any article or articles of food, device, cosmetics, household hazardous substances, and health products that are adulterated, counterfeited, misbranded, or unregistered; or any drug, in-vitro diagnostic reagents, biologicals, and vaccine that is adulterated or misbranded. In other words, the grant of such authority to the FDA Director-General necessarily includes all such powers, even those not expressly stated, that are necessary to effectuate such authority."

"Another, Section 30(6) of RA 3720, as amended by RA 9711, specifically allows the Director-General to "exercise such powers and functions as may be necessary for the effective implementation of this Act." This catch-all provision grants the Director-General all necessary and incidental powers that are reasonably germane to his or her functions under the law. This is precisely why Article VII, Section 3, paragraph (b) (2) of the IRR specifically provided that the FDA Director-General can order the padlocking of establishments suspected to have violated the FDA Act to prevent the disposition or tampering of evidence, the continuance of acts being complained of, and the flight of the respondent, as the case may be. Xxx xxx xxx. Finally, the FDA's power to temporarily seize

and close a suspected erring establishment pending hearing is akin to the "close now, hear later" policy of the Monetary Bank."

"The promotion of public health is a fundamental obligation of the State. The protection of the public, especially children, from impure or hazardous substances is a primordial governmental concern. Undoubtedly, the FDA Act, as amended was enacted in the exercise of the police power of the State in order to promote and preserve public health and safety."