# 24:6B-1 & 24:6B-2

## LEGISLATIVE HISTORY CHECKLIST

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**LAWS OF**: 2016 **CHAPTER:** 73

**NJSA:** 24:6B-1 & 24:6B-2 (Clarifies that product approval from U.S. Food and Drug Administration is not required for drug manufacturer to file registration statement, and specifies timeframe by which DOH must review registration statements.)

**BILL NO**: S2024 (Substituted for A3793)

**SPONSOR(S)** Madden Jr. and others

**DATE INTRODUCED:** April 18, 2016

**COMMITTEE:** **ASSEMBLY:** Health and Senior Services

**SENATE:** Health, Human Services and Senior Citizens

**AMENDED DURING PASSAGE:** No

**DATE OF PASSAGE:** **ASSEMBLY:** October 20, 2016

**SENATE:** June 30, 2016

**DATE OF APPROVAL:** December 5, 2016

**FOLLOWING ARE ATTACHED IF AVAILABLE:**

**FINAL TEXT OF BILL** (Introduced version of bill enacted)

**S2024**

**SPONSOR'S STATEMENT:** (Begins on page 2 of introduced bill) Yes

**COMMITTEE STATEMENT:** **ASSEMBLY**: Yes

**SENATE:** Yes

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, ***may possibly*** be found at www.njleg.state.nj.us)

**FLOOR AMENDMENT STATEMENT:** No

**LEGISLATIVE FISCAL ESTIMATE:** No

**A3793**

**SPONSOR'S STATEMENT**: (Begins on page 3 of introduced bill) Yes

**COMMITTEE STATEMENT:** **ASSEMBLY**: Yes

**SENATE:** No

**FLOOR AMENDMENT STATEMENT:** No

**LEGISLATIVE FISCAL ESTIMATE:** No

(continued)

**VETO MESSAGE:** No

**GOVERNOR'S PRESS RELEASE ON SIGNING:** Yes

**FOLLOWING WERE PRINTED:**

To check for circulating copies, contact New Jersey State Government Publications at the State Library (609) 278-2640 ext.103 or mailto:refdesk@njstatelib.org

**REPORTS:** No

**HEARINGS:** No

**NEWSPAPER ARTICLES:** Yes

"Oroho bill on pharmaceutical industry becomes law," Advertiser-News, December 15, 2016

RWH/CL

P.L.2016, CHAPTER 73, ***approved December 5, 2016***
Senate, No. 2024

**AN ACT** concerning drug manufacturing business registration and amending P.L.1961, c.52.

**BE IT ENACTED** *by the Senate and General Assembly of the State of New Jersey:*

1. Section 1 of P.L.1961, c.52 (C.24:6B-1) is amended to read as follows:

1. No person shall hereafter engage or continue to engage in a drug manufacturing business or a wholesale non-prescription drug business in this State without first filing a completed registration statement with the department. The department shall promptly review completed registration statements. Within 30 days after receipt of a registration statement, the department shall either issue registration, or shall advise the registrant, in writing, of the specific deficiencies in the registration statement. Any supplemental materials, which are submitted in response to a notice of deficiency, shall be reviewed by the department within 30 days after receipt thereof.

(cf: P.L.2005, c.206, s.1)

2. Section 2 of P.L.1961, c.52 (C.24:6B-2) is amended to read as follows:

2. The registration statement shall be signed and verified by the individuals specified in subsection (c) hereof, shall be made on forms prescribed and furnished by the commissioner, and shall state such information necessary and proper to the enforcement of this act as the commissioner may require, consistent with the provisions of this section, including:

(a) The name under which the business is conducted.

(b) The address of each location in New Jersey at which the business is to be conducted. If a wholesale non-prescription drug business is not to be conducted from a location within the State, the statement shall give the name and address of an agent resident in this State on whom process against the registrant may be served.

(c) If the registrant is a proprietorship, the name and address of the proprietor; if a partnership, the names and addresses of all partners; if a corporation, the date and place of incorporation, the names and addresses of the president and secretary thereof , and the name and address of the designated registered agent in this State; or if any other type of business association, the names and addresses of the principals of such association.

**EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.**

**Matter underlined thus is new matter.**

(d) The names and addresses of those individuals having actual administrative responsibility, which , in the case of a proprietorship, shall be the managing proprietor; in the case of a partnership, shall be the managing partners; in the case of a corporation, shall be the officers and directors; or [if] in the case of any other type of association, shall be those having similar administrative responsibilities.

(e) If the business [is to] will be conducted at more than one location in this State, the name and address of the individual in charge of each such location.

(f) A description of the business the registrant will be engaged in, and the drug products intended to be manufactured for sale or [wholesaled] wholesale. If the registrant's products have not yet been approved by the federal Food and Drug Administration, the registrant shall submit a statement confirming that an application for approval has been submitted to the federal Food and Drug Administration, or that the registrant intends to file such an application within 12 months. Approval by the federal Food and Drug Administration shall not be a condition of registration.

(g) The name and address of the individual or individuals on whom orders of the commissioner may be served.

(h) A statement as to whether the registrant [engages] will be engaged in manufacturing, compounding, processing, wholesaling, jobbing, or distribution of depressant or stimulant drugs as defined pursuant to law.

(cf: P.L.2005, c.206, s.1)

3. This act shall take effect immediately.

STATEMENT

This bill would clarify that approval by the U.S. Food and Drug Administration (FDA) is not required when a drug manufacturer is filing a registration statement. If, at the time of filing, a registrant's drug products have not yet been approved by the FDA, the registrant will be required only to submit a statement confirming that an application for approval has been submitted to the FDA, or that the registrant intends to file such an application within 12 months. The bill specifies that FDA approval will not be a condition of registration.

The bill further specifies that the Department of Health will be required to promptly review any completed registration statement submitted thereto, and, within 30 days after receipt of a registration statement, will be required to either issue the registration, or advise the registrant, in writing, of the specific deficiencies in the registration statement. The department will have an additional 30 days to review any subsequently submitted materials.

Clarifies that product approval from U.S. Food and Drug Administration is not required for drug manufacturer to file registration statement, and specifies timeframe by which DOH must review registration statements.

# SENATE, No. 2024

# STATE OF NEW JERSEY

## 217th LEGISLATURE

INTRODUCED APRIL 18, 2016

**Sponsored by:**
**Senator FRED H. MADDEN, JR.**
**District 4 (Camden and Gloucester)**
**Senator STEVEN V. OROHO**
**District 24 (Morris, Sussex and Warren)**
**Assemblyman TIM EUSTACE**
**District 38 (Bergen and Passaic)**
**Assemblyman ERIK PETERSON**
**District 23 (Hunterdon, Somerset and Warren)**
**Assemblyman HERB CONAWAY, JR.**
**District 7 (Burlington)**
**Assemblyman RAJ MUKHERJI**
**District 33 (Hudson)**
**Assemblyman DANIEL R. BENSON**
**District 14 (Mercer and Middlesex)**
**Assemblywoman ANGELA V. MCKNIGHT**
**District 31 (Hudson)**

**Co-Sponsored by:**
**Assemblyman O'Scanlon and Assemblywoman Pinkin**

**SYNOPSIS**

Clarifies that product approval from U.S. Food and Drug Administration is not required for drug manufacturer to file registration statement, and specifies timeframe by which DOH must review registration statements.

**CURRENT VERSION OF TEXT**

As introduced.

**(Sponsorship Updated As Of: 10/21/2016)**

**AN ACT** concerning drug manufacturing business registration and amending P.L.1961, c.52.

**BE IT ENACTED** *by the Senate and General Assembly of the State of New Jersey:*

1. Section 1 of P.L.1961, c.52 (C.24:6B-1) is amended to read as follows:

1. No person shall hereafter engage or continue to engage in a drug manufacturing business or a wholesale non-prescription drug business in this State without first filing a completed registration statement with the department. The department shall promptly review completed registration statements. Within 30 days after receipt of a registration statement, the department shall either issue registration, or shall advise the registrant, in writing, of the specific deficiencies in the registration statement. Any supplemental materials, which are submitted in response to a notice of deficiency, shall be reviewed by the department within 30 days after receipt thereof.

(cf: P.L.2005, c.206, s.1)

2. Section 2 of P.L.1961, c.52 (C.24:6B-2) is amended to read as follows:

2. The registration statement shall be signed and verified by the individuals specified in subsection (c) hereof, shall be made on forms prescribed and furnished by the commissioner, and shall state such information necessary and proper to the enforcement of this act as the commissioner may require, consistent with the provisions of this section, including:

(a) The name under which the business is conducted.

(b) The address of each location in New Jersey at which the business is to be conducted. If a wholesale non-prescription drug business is not to be conducted from a location within the State, the statement shall give the name and address of an agent resident in this State on whom process against the registrant may be served.

(c) If the registrant is a proprietorship, the name and address of the proprietor; if a partnership, the names and addresses of all partners; if a corporation, the date and place of incorporation, the names and addresses of the president and secretary thereof , and the name and address of the designated registered agent in this State; or if any other type of business association, the names and addresses of the principals of such association.

(d) The names and addresses of those individuals having actual administrative responsibility, which , in the case of a proprietorship, shall be the managing proprietor; in the case of a partnership, shall

**EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.**

**Matter underlined thus is new matter.**

be the managing partners; in the case of a corporation, shall be the officers and directors; or [if] in the case of any other type of association, shall be those having similar administrative responsibilities.

(e) If the business [is to] will be conducted at more than one location in this State, the name and address of the individual in charge of each such location.

(f) A description of the business the registrant will be engaged in, and the drug products intended to be manufactured for sale or [wholesaled] wholesale. If the registrant's products have not yet been approved by the federal Food and Drug Administration, the registrant shall submit a statement confirming that an application for approval has been submitted to the federal Food and Drug Administration, or that the registrant intends to file such an application within 12 months. Approval by the federal Food and Drug Administration shall not be a condition of registration.

(g) The name and address of the individual or individuals on whom orders of the commissioner may be served.

(h) A statement as to whether the registrant [engages] will be engaged in manufacturing, compounding, processing, wholesaling, jobbing, or distribution of depressant or stimulant drugs as defined pursuant to law.

(cf: P.L.2005, c.206, s.1)

3. This act shall take effect immediately.

STATEMENT

This bill would clarify that approval by the U.S. Food and Drug Administration (FDA) is not required when a drug manufacturer is filing a registration statement. If, at the time of filing, a registrant's drug products have not yet been approved by the FDA, the registrant will be required only to submit a statement confirming that an application for approval has been submitted to the FDA, or that the registrant intends to file such an application within 12 months. The bill specifies that FDA approval will not be a condition of registration.

The bill further specifies that the Department of Health will be required to promptly review any completed registration statement submitted thereto, and, within 30 days after receipt of a registration statement, will be required to either issue the registration, or advise the registrant, in writing, of the specific deficiencies in the registration statement. The department will have an additional 30 days to review any subsequently submitted materials.

SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

STATEMENT TO

**SENATE, No. 2024**

# STATE OF NEW JERSEY

DATED: MAY 16, 2016

The Senate Health, Human Services and Senior Citizens Committee reports favorably Senate Bill No. 2024.

As amended by the committee, this bill would clarify that approval by the U.S. Food and Drug Administration (FDA) is not required when a drug manufacturer is filing a registration statement. If, at the time of filing, a registrant's drug products have not yet been approved by the FDA, the registrant will be required only to submit a statement confirming that an application for approval has been submitted to the FDA, or that the registrant intends to file such an application within 12 months. The bill specifies that FDA approval will not be a condition of registration; however, it also expressly provides that nothing in the bill's provisions may be deemed to obviate, or to otherwise limit, the provisions of the federal Food and Drug

The bill further specifies that the Department of Health will be required to promptly review any completed registration statement submitted thereto, and, within 30 days after receipt of a registration statement, will be required to either issue the registration, or advise the registrant, in writing, of the specific deficiencies in the registration statement. The department will have an additional 30 days to review any subsequently submitted materials.

ASSEMBLY HEALTH AND SENIOR SERVICES COMMITTEE

STATEMENT TO

**SENATE, No. 2024**

# STATE OF NEW JERSEY

DATED: OCTOBER 6, 2016

The Assembly Health and Senior Services Committee reports favorably Senate Bill No. 2024.

This bill clarifies that approval by the U.S. Food and Drug Administration (FDA) is not required when a drug manufacturer is filing a registration statement with the New Jersey Department of Health (DOH). If, at the time of filing, a registrant's drug products have not yet been approved by the FDA, the registrant will be required only to submit a statement confirming that an application for approval has been submitted to the FDA, or that the registrant intends to file such an application within 12 months. The bill specifies that FDA approval will not be a condition of registration.

The bill further requires DOH to promptly review any completed registration statements it receives, and, within 30 days after receipt of a registration statement, to either issue the registration or advise the registrant, in writing, of the specific deficiencies in the registration statement. DOH will have an additional 30 days to review any supplemental materials submitted in response to a notice of deficiency.

As reported by the committee, this bill is identical to Assembly Bill No. 3793, which the committee also reported on this date.

# ASSEMBLY, No. 3793

# STATE OF NEW JERSEY

## 217th LEGISLATURE

INTRODUCED MAY 23, 2016

**Sponsored by:**
**Assemblyman TIM EUSTACE**
**District 38 (Bergen and Passaic)**
**Assemblyman ERIK PETERSON**
**District 23 (Hunterdon, Somerset and Warren)**
**Assemblyman HERB CONAWAY, JR.**
**District 7 (Burlington)**
**Assemblyman RAJ MUKHERJI**
**District 33 (Hudson)**
**Assemblyman DANIEL R. BENSON**
**District 14 (Mercer and Middlesex)**
**Assemblywoman ANGELA V. MCKNIGHT**
**District 31 (Hudson)**

**Co-Sponsored by:**
**Assemblyman O'Scanlon and Assemblywoman Pinkin**

**SYNOPSIS**

Clarifies that product approval from U.S. Food and Drug Administration is not required for drug manufacturer to file registration statement, and specifies timeframe by which DOH must review registration statements.

**CURRENT VERSION OF TEXT**

As introduced.

**(Sponsorship Updated As Of: 10/21/2016)**

**AN ACT** concerning drug manufacturing business registration and amending P.L.1961, c.52.

**BE IT ENACTED** *by the Senate and General Assembly of the State of New Jersey:*

1. Section 1 of P.L.1961, c.52 (C.24:6B-1) is amended to read as follows:

1. No person shall hereafter engage or continue to engage in a drug manufacturing business or a wholesale non-prescription drug business in this State without first filing a completed registration statement with the department. The department shall promptly review completed registration statements. Within 30 days after receipt of a registration statement, the department shall either issue registration, or shall advise the registrant, in writing, of the specific deficiencies in the registration statement. Any supplemental materials, which are submitted in response to a notice of deficiency, shall be reviewed by the department within 30 days after receipt thereof.

(cf: P.L.2005, c.206, s.1)

2. Section 2 of P.L.1961, c.52 (C.24:6B-2) is amended to read as follows:

2. The registration statement shall be signed and verified by the individuals specified in subsection (c) hereof, shall be made on forms prescribed and furnished by the commissioner, and shall state such information necessary and proper to the enforcement of this act as the commissioner may require, consistent with the provisions of this section, including:

(a) The name under which the business is conducted.

(b) The address of each location in New Jersey at which the business is to be conducted. If a wholesale non-prescription drug business is not to be conducted from a location within the State, the statement shall give the name and address of an agent resident in this State on whom process against the registrant may be served.

(c) If the registrant is a proprietorship, the name and address of the proprietor; if a partnership, the names and addresses of all partners; if a corporation, the date and place of incorporation, the names and addresses of the president and secretary thereof , and the name and address of the designated registered agent in this State; or if any other type of business association, the names and addresses of the principals of such association.

(d) The names and addresses of those individuals having actual administrative responsibility, which , in the case of a proprietorship, shall be the managing proprietor; in the case of a partnership, shall

**EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.**

**Matter underlined thus is new matter.**

be the managing partners; in the case of a corporation, shall be the officers and directors; or [if] in the case of any other type of association, shall be those having similar administrative responsibilities.

(e) If the business [is to] will be conducted at more than one location in this State, the name and address of the individual in charge of each such location.

(f) A description of the business the registrant will be engaged in, and the drug products intended to be manufactured for sale or [wholesaled] wholesale. If the registrant's products have not yet been approved by the federal Food and Drug Administration, the registrant shall submit a statement confirming that an application for approval has been submitted to the federal Food and Drug Administration, or that the registrant intends to file such an application within 12 months. Approval by the federal Food and Drug Administration shall not be a condition of registration.

(g) The name and address of the individual or individuals on whom orders of the commissioner may be served.

(h) A statement as to whether the registrant [engages] will be engaged in manufacturing, compounding, processing, wholesaling, jobbing, or distribution of depressant or stimulant drugs as defined pursuant to law.

(cf: P.L.2005, c.206, s.2)

3. This act shall take effect immediately.

STATEMENT

This bill would clarify that approval by the U.S. Food and Drug Administration (FDA) is not required when a drug manufacturer is filing a registration statement. If, at the time of filing, a registrant's drug products have not yet been approved by the FDA, the registrant will be required only to submit a statement confirming that an application for approval has been submitted to the FDA, or that the registrant intends to file such an application within 12 months. The bill specifies that FDA approval will not be a condition of registration.

The bill further specifies that the Department of Health will be required to promptly review any completed registration statement submitted thereto, and, within 30 days after receipt of a registration statement, will be required to either issue the registration, or advise the registrant, in writing, of the specific deficiencies in the registration statement. The department will have an additional 30 days to review any subsequently submitted materials.

ASSEMBLY HEALTH AND SENIOR SERVICES COMMITTEE

STATEMENT TO

# ASSEMBLY, No. 3793

# STATE OF NEW JERSEY

DATED: OCTOBER 6, 2016

The Assembly Health and Senior Services Committee reports favorably Assembly Bill No. 3793.

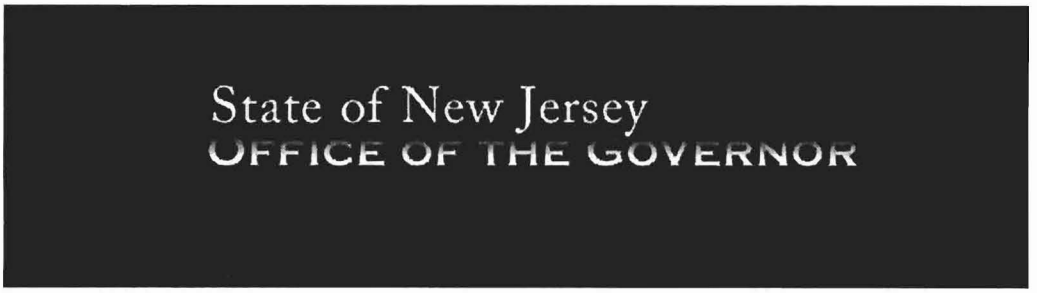
This bill clarifies that approval by the U.S. Food and Drug Administration (FDA) is not required when a drug manufacturer is filing a registration statement with the New Jersey Department of Health (DOH). If, at the time of filing, a registrant's drug products have not yet been approved by the FDA, the registrant will be required only to submit a statement confirming that an application for approval has been submitted to the FDA, or that the registrant intends to file such an application within 12 months. The bill specifies that FDA approval will not be a condition of registration.

The bill further requires DOH to promptly review any completed registration statements it receives, and, within 30 days after receipt of a registration statement, to either issue the registration or advise the registrant, in writing, of the specific deficiencies in the registration statement. DOH will have an additional 30 days to review any supplemental materials submitted in response to a notice of deficiency.

As reported by the committee, this bill is identical to Senate Bill No. 2024, which the committee also reported on this date.

# Governor Chris Christie Signs Legislation Strengthening New Jersey Residents' Security

Monday, December 5, 2016 Tags: Bill Action




*Takes Action on Pending Legislation*

**Trenton, NJ –** Governor Chris Christie today signed a package of legislation designed to make New Jerseyans safer. The measures include requirements for schools to conduct yearly security training alongside first responders (A-3349/S-2438) and that existing and any new school architectural plans include certain security measures (A-3348/S-2439). Additionally, A-1946/S-1257 expands domestic violence statutes to include cyber-harassment.

"We must make every effort to ensure New Jersey citizens are safe and secure whether they are in their school buildings or online," said Governor Christie. "These new laws will require safety measures to be built into new school construction and all school personnel to be trained annually on safety and security. Additionally, I have signed a bill to address one of the fastest growing threats we face in the 21st century, cyber-harassment. This new law will help victims of domestic violence whose abusers choose to attack through the web and social media outlets."

Governor Chris Christie also took action on the following legislation:

**BILL SIGNINGS:**

**S-384/A-3470 (Greenstein/Johnson)** - Requires correctional facilities to provide inmates with prescription medication that was prescribed for chronic conditions existing prior to incarceration

**S-743/ACS for A-2761 (Beach, Sarlo, Ruiz/Mazzeo, Zwicker, Jasey, Vainieri Huttle, Schaer, Jones, Eustace, Land, Gusciora, Andrzejczak, Downey, Houghtaling, Benson, Mukherji, McKeon, Lampitt)** - Directs Higher Education Student Assistance Authority to forgive certain student loans in the event of student borrower's death or total and permanent disability and grant deferment for temporary total disability

**S-1041/A-1449 (Weinberg, Gordon/Lampitt, Benson, Vainieri Huttle, Tucker, Wimberly, Downey)** - Requires DHS to develop timeline for use by individuals with developmental disabilities to gain benefit of State and federal programs; requires posting timeline on DHS, DCF, and DOE websites

**S-2024/A-3793 (Madden, Oroho/Eustace, Peterson, Conaway, Mukherji, Benson, McKnight)** - Clarifies that product approval from U.S. Food and Drug Administration is not required for drug manufacturer to file registration statement, and specifies timeframe by which DOH must review registration statements

**S-2337/A-3985 (Sacco, Allen/Jimenez, O'Scanlon, Mukherji, Benson, Peterson)** - Permits law enforcement agencies to buy firearms directly from manufacturers; clarifies permits and identification cards not required

**S-2338/A-3914 (Whelan, Stack/Mazzeo)** - Allows existing rural development areas zoned for industrial use under pinelands comprehensive management plan to be included as eligible areas under certain business incentive programs

**A-1878/S-2404 (Wimberly/Rice)** - Increases to under $15,000 from under $10,000 amount of permitted annual compensation paid to TPAF retiree reemployed as athletic coach by former school district within 180 days of



## More Information

Senate Bill No 51

Senate Bill No 92

retirement

**A-2519/S-1152 (DeAngelo, Holley, Mazzeo, Downey, McKnight/Greenstein, Beach)** - Directs Attorney General to develop plan to disseminate Amber and Silver Alert information through social media

**A-3662/S-2374 (Schaer, Caride, Vainieri Huttle, Mukherji, McKnight, Chiaravalloti, Quijano/Weinberg, Pou)** – "Rosa-Bonilla Family Act"; concerns development of carbon monoxide poisoning educational program for drivers

**A-3748/S-2115 (DeAngelo, Eustace, Mukherji, Holley, Benson, Beach/Cruz-Perez)** - Requires DMVA to create registry for organizations providing services to veterans

**AJR-23/SJR-30 (Andrzejczak, Land, Wimberly, Taliaferro/Van Drew)** - Designates third weekend in October each year as "Shuck, Sip, and Slurp Weekend" to promote NJ oysters, wine, and beer

**AJR-24/SJR-36 (Andrzejczak, Houghtaling/Van Drew, Connors)** - Declares aquaculture an important State economic driver and urges State to include aquaculture industry in its economic development plans

**AJR-25/SJR-14 (Land, Andrzejczak/Van Drew)** - Recognizes Delaware Bayshore as region of special significance in NJ

**AJR-98 (Space, Taliaferro)** - Designates June of each year as "Native Plant Appreciation Month"

**BILLS VETOED**:

**S-51/A-547 (Lesniak, Cunningham/Pinkin, Sumter, Vainieri Huttle, Gusciora, Muoio) – ABSOLUTE -** Restricts use of isolated confinement in correctional facilities

**S-92/A-2815 (Whelan/Mosquera, Jones, DeAngelo, Mazzeo, Johnson, Houghtaling) – CONDITIONAL -** Revises "Overseas Residents Absentee Voting Law" to mirror federal law; permits overseas voters to vote in any election; permits use of federal write-in absentee ballot to vote, register or request ballot for all elections

**Press Contact:**
Brian Murray
609-777-2600